VOLUME 13 NUMBER 2

Food·Drug·Cosmetic Law

Journal

FEBRUARY • 1958

Questions and Answers from FDA-FLI Conference on November 26, 1957

Food, Food Science and the Food Group: A 25-Year Review . . . . . .

A. J. AMOS, F. R. I. C.

Some Landmarks Along the Development of the Food Law and Its Administration Since World War II

SAMUEL A. McCAIN

See Table of Contents for Articles in This Issue

A COMMERCE CLEARING HOUSE PUBLICATION

PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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REPORTS

TO THE READER

About the Authors

Featured in the February JOURNAL is a Food and Drug Administration panel discussion of questions submitted by industry conferees at an all-day informal meeting promoted by The Food Law Institute, Inc., and held on November 26, 1957, at the United States Department of Health, Education, and Welfare Building, in Washington, D. C. The papers delivered by FDA representatives before this question-answer session appeared in our December, 1957 issue.

A. J. Amos, F. R. I. C., holds degrees of Bachelor of Science and Doctor of Philosophy. Dr. Amos' contribution "Food, Food Science and the Food Group: A 25-Year Review" is derived from an address before the Food Group of the Society of Chemical Industry [Great Britain] marking his retirement as chairman of the group. The paper is reprinted from *Chemistry and Industry* for October 19, 1957.

Samuel A. McCain, of New York City, is general counsel for Corn Products Refining Company. He has been a member of the editorial advisory board of this publication since 1946.

After receiving an A. B. degree from the University of Missouri in 1930, **Marion A. Hoy,** an attorney, of Oak Park, Illinois, joined the staff of the research department of the American Can Company. From 1935 to 1948, Mr. Hoy represented that company, teaching ten-day courses in microanalyses of canned foods to canners, food technologists and university students at the following institutions: Purdue University; New York State Agricultural Experiment Station, Cornell University; the University of Arkansas; Macdonald College, Ste. Anne de Bellevue, Quebec; Ontario Agricultural College, Guelph, Ontario; and Dominion Experimental Station, Summerland, British Columbia. He received a J. D. degree from John Marshall Law School in 1939, and an LL. M. degree in 1940. In 1948, he resigned to devote full time to the private practice of law.

Mr. Hoy successfully represented canners in two important cases—one, in 1953, involving the question of fly eggs and maggots in canned tomatoes and the other, in 1955-1956, involving questions of insanitary conditions in a factory and adulteration of tomato paste. He would seem well qualified to write on the subject matter which he has chosen for his contribution to this issue.

Bernard L. Oser, writer of "The Functional Value of Food Additives" and of the continuing feature, "The Scientists' Forum" — both appearing here—is director of Food and Drug Research Laboratories, of New York City.

"Christopher Comments" is written by **Thomas W. Christopher,** associate dean and professor of law, Emory University Law School, Atlanta, Georgia.

Meetings of Food and Drug Men

New York State Bar Association—Section on Food, Drug and Cosmetic Law.—The following officers were elected at the January 29 annual meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association: chairman, Charles Wesley Dunn, of New York City; vice chairman, A. M. Gilbert, of New York City; secretary, Irving H. Jurow, of Bloomfield, New Jersey. Other executive-committee members are Walton M. Wheeler, Jr., of Indianapolis; Harold Harper, of New York City; and Michael F. Markel, of Washington, D. C.

The standing-committee chairmen remain the same: committee on food law, Samuel A. McCain, of New York City; committee on drug law, James F. Hoge, of New York City; committee on cosmetic law, Richard G. Moser, of New York City; committee on food standards, H. Thomas Austern, of Washington, D. C.; committee on beverage law, John T. Tabor, of St. Louis; committee on chemicals, Charles S. Maddock, of Wilmington, Delaware; committee on uniform state food, drug and cosmetic laws, Michael F. Markel, of Washington, D. C.; committee on product liability law, Bradshaw Mintener, of Washington, D. C.

The section adopted a resolution for an amendment of the Federal Food, Drug, and Cosmetic Act to provide flexible food standards of identity. In this situation the standard would fix the essential composition of a food to preserve its product integrity, but the manufacturer would be free to add consistent optional ingredients, in his discretion, to improve the food, provided their use does not violate the general adulteration and misbranding provisions of the Act.

Also, at the meeting, the section adopted resolutions on the death of former Food and Drug Administration Commissioner Charles W. Crawford and to upgrade the salaries of key FDA officials.

Gordon Research Conferences.—The Gordon Research Conferences for 1958 will be held from June 9 to August 29 at Colby Junior College, New London, New Hampshire; New Hampton School, New Hampton, New Hampshire; and Kimball Union Academy, Meriden, New Hampshire. The conferences — established to stimulate research in universities, research foundations and industrial laboratories—are held mornings and evenings, Monday through Friday, with the exception of Friday evenings.

Persons interested in attending a conference or in receiving further information may send their applications to the director, W. George Parks, Department of Chemistry, University of Rhode Island, Kingston, Rhode Island. During the time of the conferences, mail may be addressed to Colby Junior College. Each applicant must state the institution or company with which he is connected and the type of work in which he is most interested. Attendance at each conference is limited to 100.

According to Mr. Parks, the program's purpose is "not to review the known fields of chemistry but primarily to bring experts up to date as to the latest developments, analyze the significance of these developments, and to provoke suggestions as to underlying theories and profitable methods of approach for making new progress."

Among the conference features will be: "The Laboratory Animal in Toxicity Studies," with O. G. Fitzhugh as chairman, and Lloyd W. Hazleton and Bernard L. Oser discussing "The Choice of Animals as Related to the Interpretation of Toxicity Studies"; and "Metabolic and Biochemical Investigations in Toxicity Evaluations," with Arnold J. Lehman, M. D., as chairman. There will also be a panel discussion on training of toxicologists.

WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

Monthly Report, Issued January 29, 1958.—Sixty-six seizures were made in December of contaminated food totaling 181 tons, according to a Food and Drug Administration report released on January 29.

Included were 18 seizures of nuts, aggregating 38 tons, to protect Christmas holiday purchasers from insect-damaged, rancid, moldy and shriveled nuts. In addition, one packer voluntarily destroyed seven tons of Brazil nuts after he had received a report of FDA analysis of samples of mixed nuts collected at his plant. To separate the Brazil nuts from the mixture, employees opened more than 34,000 one-pound cellophane bags of mixed nuts for sorting on a conveyor belt.

More than 8,400 bushels of spinach were traced and seized at cities in the East and Midwest because the spinach was contaminated with residues of DDT in excess of the legal tolerance.

Ninety-eight firms voluntarily destroyed 72 tons of unfit foods, or diverted them to nonfood use, after FDA inspectors called attention to their condition. The inspectors, revisiting plants where sanitary improvements had been suggested earlier, reported that $270,000 was spent by 14 firms to correct conditions that were permitting contamination of the food. The corrections included repairs and construction to protect food from insects, rodents and birds; installation of modern, sanitary equipment; and stepped-up sanitation and extermination activities.

Ten seizures were made of misbranded foods, FDA reported. Included were butter, canned peaches and canned beans that failed to meet legal standards; debased seasonings; and short-weight coffee.

Eleven seizures of drugs included five subpotent items and five products promoted with false and misleading therapeutic claims. Repacked physicians' samples of nine prescription drugs which failed to bear labeling required for commercial distribution were seized in the possession of a sales company which had collected them from various sources. Eight firms voluntarily destroyed deteriorated drugs originally valued at $54,820.

Synthetically Produced Colors—Hearing.—A public hearing will be held March 10 to determine if certain synthetically produced colors for use in foods should be tested and certified as harmless by FDA before they are mar-

keted, the Administration announced on January 28.

The colors involved are chemically similar to colors which can be extracted from natural sources. The most important of them is synthetic carotene, used for coloring margarine and butter.

At issue are different proposals by FDA and by a color manufacturer, for revising the definition of a coal-tar color as it appears in FDA regulations. The agency published both its proposal and the manufacturer's proposal on June 7, 1957. Subsequently, FDA issued an order adopting its own proposal, but held the order in abeyance because of objections from that manufacturer and others. The next step in the procedure is the public hearing.

The change in definition proposed by the Commissioner of Food and Drugs would exempt from color certification carbon black, caramel, and a number of colors derived from vegetable sources. However, FDA testing and certification would be required for synthetically produced colors such as synthetic carotene, but carotene produced from carrots would not have to be certified.

The manufacturer proposed a definition that would exempt certain synthetic compounds as well as colors from natural sources.

A prehearing conference was held February 20, for the purpose of scheduling subjects and witnesses. Persons who expected to take an active part in the formal hearing were invited to attend this preliminary meeting.

Budget Increase Recommended.—In its 1959 budget request, the Department of Health, Education, and Welfare listed expenses of the Food and Drug Administration as follows: "actual 1957—$7,798,909; estimated 1958—$10,554,500; estimated 1959—$10,664,500; increase—1%."

The Department went on to state:

"The 1959 budget request would permit a slight further expansion of operations of the Food and Drug Administration. The requested funds will enable FDA to increase the number of plant inspections from 18,700 to an estimated 19,600. There would be corresponding increases in the number of samples collected and the number of analyses and other examinations performed by FDA laboratories.

"The program for improvement and modernization of scientific equipment would be continued at a somewhat slower pace than in 1958.

"In addition, funds would be available for initial staffing of a new FDA district office in Detroit, Michigan, which is being established and equipped under this year's appropriation."

Last Year's Activities—Summing-up.—In his 1957 year-end statement, HEW Secretary Marion B. Folsom had this to say of FDA activities:

"The job of the Food and Drug Administration grows more complex every year as American consumption increases in quantity and variety. During the year $62 billion worth of foods, drugs, and cosmetics moved through some 100,000 factories and warehouses which were subject to Federal inspection and laboratory analysis. An expanded program, begun this year, permitted the FDA to inspect more establishments, increase its supervision of new drugs, conduct more basic scientific research and devote further attention to establishment and enforcement of food standards. FDA also intensified its efforts against fraudulent practices in the medical and nutritional fields."

Notices-of-Judgment Pamphlet Issued.—Judgments in drugs-and-devices cases Nos. 5081-5100, instituted under the Federal Food, Drug, and Cosmetic Act are summarized in a pamphlet recently issued by the Department of Health, Education, and Welfare.

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Vol. 13, No. 2 February, 1958

Food·Drug·Cosmetic Law
Journal

Questions and Answers from FDA–FLI Conference on November 26, 1957

This Food and Drug Administration Panel Discussion of Industry Conferees' Questions Was a Feature of the Conference, Held to Promote a Closer Relationship and Better Understanding Between Food Industry and FDA in Its Administration of the Federal Act

FDA Educational Action

The Citizens Advisory Committee on the Food and Drug Administration recommended more FDA educational action for the basic purpose of securing a maximum voluntary compliance with the Federal Food, Drug, and Cosmetic Act, on an informal basis, in due balance with its necessary court enforcement. Such action is especially required to solve the complex scientific problems created by the modern advance in food manufacture—through their joint FDA-food industry discussion at the highest scientific levels. Moreover, the American Bar Association Section on Food, Drug, and Cosmetic Law has favorably discussed an amendment of this Act to direct this constructive educational action, on which it is now silent.

Question.—

(1) Will FDA approve such an amendment written in a due form?

Answer.—

(1) Since Section 705 of the Food, Drug, and Cosmetic Act already provides for publicity which would include the issuance of educational materials, we believe that an amendment to the law is not necessary.

Question.—

(2) What further educational action is now planned or contemplated by FDA, from a food standpoint?

Answer.—

(2) We are expanding our facilities for educational action and are in process of setting up an organizational structure that will support the expanded program. While these will be directed to the entire field of foods, drugs, devices and cosmetics, a large portion of the activities of the unit will, of course, be devoted to food matters, since the bulk of our time is on food work.

Question.—

(3) Would it not be a good idea to make this FDA-FLI food educational conference a permanent annual plan, with its area appropriately broadened each year to include, for example and where indicated, a symposium discussion of current scientific problems under the Food, Drug, and Cosmetic Act?

Answer.—

(3) We will welcome suggestions from those who are present at this conference as to the desirability of holding further food conferences. If the recommendation is for further conferences, we would welcome also suggestions as to the subject matter to be considered at future sessions.

Trade Correspondence

The citizens advisory committee also recommended that FDA resume the valuable publication of its correspondence with manufacturers (and others) on the practical meaning and application of the Food, Drug, and Cosmetic Act, for the guiding information of all concerned.

Question.—

(1) When will this publication be resumed?

Answer.—

(1) We have been issuing formal statements of policy for several years and we are publishing informal statements of policy in the *Federal Register* beginning November 30. They will not be referred to as "Trade Correspondence" because they will be drawn not only from trade correspondence, but also from any other source where pertinent information is available.

Question.—

(2) Will it include all correspondence since its publication was discontinued?

Answer.—

(2) We think the statements to be issued on November 30 will bring us reasonably up to date. We do not plan at this time to review all of the correspondence that has issued since 1946 or 1947 when the old "Trade Correspondence" letters were discontinued.

Question.—

(3) Should not FDA also systematically report (for example, monthly) on its organizational and operational progress, in addition to its regular enforcement reports, likewise for the guiding information of all concerned?

Answer.—

(3) The Administration does systematically report on its operational progress in its annual reports to the Secretary of Health, Education, and Welfare, copies of which are available for general distribution. More frequent reports are made to the Secretary but are not published. We do not have any plans to make public our interim progress reports to the Secretary.

We are required by law to publish organizational changes in the *Federal Register* before they are made, and such publications have appeared as necessary.

Food Programs

Question.—

(1) What are the current FDA administrative and enforcement programs in policy and detail, from a food standpoint?

Answer.—

(1) Administration policy regarding all programs, including food programs, has been stated in the citizens advisory committee report. This provides for priority in program development and execution based on (a) hazards to health, (b) decomposition, contamination, or insanitary conditions and (c) economic violations.

The food programs and field-work planning are based on a division of foods into related groups called "Commodity Codes." Each commodity area is covered by general programs or specific subject programs such as cheese production in the dairy group. Programs are usually investigational or regulatory.

Current and in-process-of-development regulatory and investigational programs include the following as examples:

(a) *Grain sanitation*—directed toward improvement in sanitary care of grain intended for food products.

(b) *Macaroni products*—relating to sanitation in macaroni production and adherence to existing food standards.

(c) *Bakery products*—relating to sanitation in production, informative labeling, net weight and enrichment practices.

(d) *Inconspicuous labeling*—to provide the consumer with legally required information in a conspicuous declaration.

(e) *Pesticide residues*—consumer protection against poisons used on agricultural products.

(f) *Low-sodium foods*—relating to accurate labels for persons on restricted diets.

(g) *Tomato products*—relating to sanitation in tomato products and standards compliance.

(h) *Food-storage warehousing*—directed toward elimination of rodent and insect contamination and other adulterations of foods while held in storage.

(i) *Dairy products*—relating to the quality of cream and milk, sanitation, and compliance with standards.

(j) *Radioactive isotopes in food*—a look toward the future when this may become a problem related to peaceful uses of atomic energy.

Question.—

(2) What is the now planned development of these programs as to policy and in detail?

Answer.—

(2) The development of programs contemplates their execution in terms of regulatory action, investigative work to appraise compliance and education of industry to promote voluntary compliance. The allocation of manpower to accomplish these objectives is based in part on the density of industry and the degree of compliance or extent of the problem. Each district is given an allocation of time to devote to these various programs.

The revision of existing programs and development of new programs is a matter of priority within the capability of the planning staff. For example: In response to consistent consumer complaints concerning foreign materials in bottled beverages, we are completing

a program in the general area of soft drinks. Other programs are in the investigative stage to determine the need for, and nature of, regulatory action and appropriate educational work. Consideration of possibly deceptive packaging is a current example.

Food Violations

Question.—

(1) How many court proceedings were instituted last year charging food violations of the Food, Drug, and Cosmetic Act? State the kind of proceedings and nature of charges and final judgments, on a classified basis.

Answer.—

(1) Total Food Violations, Fiscal Year 1957:

Seizures	672	
Prosecutions	77	
Injunctions	8	
(a) Seizure breakdown:		
Health	59	1,047 tons
Filth and Decomposition (total)	538	5,657 tons
(Portion of this total representing contamination after shipment	249	2,440 tons)
Economic	75	104 tons
(b) Prosecution breakdown:		
Health	3	
Filth and Decomposition	62	
Economic	12	
(c) Injunction breakdown:		
Health	0	
Filth and Decomposition	5	
Economic	3	
(d) Cases terminated, July 1, 1956-June 30, 1957:		
Total	71	
Pleas:		
Guilty	53	
Not guilty	3	(convicted on trial)
Nolo contendere	15	
Total fines	$65,806	
Total prison terms	1½ years	

Question.—

(2) Are food violations becoming more or less frequent, broadly speaking?

Answer.—

(2) This is a difficult question to answer since there are so many variables. Figures over the past three years suggest that violations are lessening. When we begin to get returns from an added force with better coverage, we should have better data.

Question.—

(3) What is the current trend of food violations, on a classified basis?

Answer.—

(3) Indications—and nothing more—are that the trend is toward economic violations. As we get better coverage in that field, we can better appraise the over-all situation.

Question.—

(4) What further educational action can the food industry take to prevent such violations, on that basis?

Answer.—

(4) (a) Better control procedures in plants;
(b) More careful scrutiny of labels and labeling.

Question.—

(5) To what extent are food manufacturers now consulting FDA to avoid such violations, actually and comparatively?

Answer.—

(5) No blanket answer can be given. Some firms consistently seek comment on proposed labeling and plant practices. Others never do. We are glad to offer comment within our fields of competence when asked to do so and if we are furnished complete background information on the question—such as quantitative formula data. It is not entirely clear to us why more firms do not avail themselves of this service, which we think is an educational aspect of good enforcement.

Factory Inspection

Questions.—

Has the amended factory inspection law of the Food, Drug, and Cosmetic Act proved administratively adequate and effective?

How many factory inspectors does FDA now have?

What is the current FDA program for inspecting food factories?

How many food factories are now inspected each year?

Answers.—

We have now had four years' experience with the revised establishment-inspection section of the law which amended Section 704 of the Act. There are some deficiencies which were recognized before the amendment was enacted. Despite these, the amendment works reasonably well. The clearer language and authority have helped both the inspector and the manufacturer to understand the intent of Congress in this area. Compliance of food manufacturers has been high and, although we have infrequently found it necessary to take regulatory action against some firms in order formally to impress the statutory requirements upon them, the number of actions has been very low.

We now have about 340 food and drug inspectors. About 60 of these are new appointees in training status and not yet ready to perform independent work. About 50 per cent of the time of an inspector is spent on the basic job of inspection of establishments and the remainder of his time on sample collections, special investigations of various kinds, and travel.

During fiscal year 1957, 20,241 establishment inspection of all kinds were performed, of which 16,650 were in the food field. During the present year, we expect proportionately higher coverage with our modest increase in the inspectional staff.

Food Samples

Question.—

(1) What is the current FDA program for collecting and examining food samples to enforce the Food, Drug, and Cosmetic Act?

Answer.—

(1) Samples fall into several categories:

(a) Factory food samples—raw material in process or finished material samples collected during an establishment inspection for laboratory examination to determine compliance.

(b) Subjective samples—samples usually collected after establishment inspection to confirm inspection operation or compliance with the Act.

(c) Objective samples—coverage of selected areas to determine a broad picture of industry compliance.

(d) Consumer complaints—legitimate complaints of consumers given attention by the collection of samples from the parent lot of the alleged offending product. Such followup has frequently led to the finding of violative, and sometimes dangerous, products.

Question.—

(2) Does FDA now contemplate any revision of this program? If so, in what detail?

Answer.—

(2) The revision we contemplate is to collect more samples as our staff grows, and thus get a better picture of the situation in both food and drug fields.

Dietary Foods

Question.—

(1) Does FDA plan to revise the dietary food regulations under the Federal Food, Drug, and Cosmetic Act?

Answer.—

(1) The present regulations were promulgated more than 10 years ago; although we have done some patchwork on them, such as the change in the niacin requirement and the regulations for low-sodium food, they are out of date. We do plan to revise them as soon as possible.

Question.—

(2) If so, what is the planned revision as to policy and in detail?

Answer.—

(2) We are not in a position at this time to furnish the details of the revision of these regulations, since the matter has not been studied that carefully. The cooperation of the food industry will be solicited, however, in revising these regulations.

Question.—

(3) What is FDA doing to correct the false charges of food cranks and faddists and to prevent their wrongful commercial practices?

Answer.—

(3) A substantial regulatory effort is being expended in an effort to control the activities of food cranks and faddists who exploit the

public by making exaggerated and unwarranted therapeutic claims for various types of health foods.

We have filed several criminal cases against the principal promoters, and two of them are now serving prison terms. We have convicted house-to-house salesmen of dietary foods based on oral misrepresentations. We have also made many seizures.

In addition to the regulatory program, we have also expended considerable effort in the educational field. This is one area where we have made considerable progress in complying with the citizens committee's recommendation on education. An educational circular entitled *Food Facts vs. Food Fallacies* was developed as a part of the press kit for World Health Day, which was on April 7, 1957. This circular attracted wide attention and has been very favorably reported in the newspapers. The Better Business Bureau has made extensive distribution of the circular and it has been called to the attention of the nutritionists and public-health authorities throughout the country.

All of our districts have done considerable local publicity on health-food promoters during the past year.

We believe that proper action in this field is through a combination of vigorous regulatory action and a strong educational program to correct misinformation about our food supply.

Question.—

(4) What can FDA and the food industry do better to protect the consumer from the commercial exploitation of fraudulent food and drugs?

Answer.—

(4) As far as FDA is concerned, we believe that our regulatory and educational program should be accelerated, and this will be done as our facilities are increased. We think that this is a field in which the food industry can materially support our efforts. We suggest that you consider the desirability of launching a nation-wide educational program to combat nutritional quackery. There is a need to educate the people on good nutrition and the adequacy of our food supply. In this connection, we would be happy to see the circular *Food Facts vs. Food Fallacies* given wide distribution.

Other organizations interested in this field would no doubt be interested in joining such a program.

We think also that the industry itself can do a considerable amount in policing its members to prevent exaggerated and unwarranted claims for our basic foods.

Food Colors

Question.—

(1) What is the revision of the administrative regulations listing coal-tar colors that are harmless and suitable for use in food, which has been recently made and which is further planned or contemplated?

Answer.—

(1) A proposed revision of the coal-tar color regulations, published in the *Federal Register* of January 24, 1957, had the effect of removing from the list of colors eligible for certification for use in food four yellow colors—that is, FD&C Nos. 1, 2, 3 and 4. An order was published in May of 1957, promulgating the proposed regulation; however, objections were filed by parties who would be adversely affected and requests made for a hearing on the matter. In view of these objections, a notice of a stay of the effectiveness of the order was published pending a hearing. The hearing date has not as yet been set.

There was also published in January another proposed revision of the coal-tar color regulations, which had to do with the definition of the term "coal-tar color." There were two proposals—one by the Department of Health, Education, and Welfare and the other by a manufacturer. An order was published on this proposal in June, 1957; this also has resulted in the receipt of objections by parties adversely affected and in requests for a hearing. The hearing date has not as yet been set, but it is hoped that it can be arranged in the near future.

Question.—

(2) Will FDA act in the pending coal-tar color litigation under the Food, Drug, and Cosmetic Act to have the Supreme Court decide the question as to whether the administrator of this Act can establish safe tolerances for inherently toxic coal-tar colors used in food?

Answer.—

(2) A previous delisting order involving three colors (FD&C Oranges Nos. 1 and 2 and Red No. 32) has been the subject of litigation. The United States Court of Appeals for the Second Circuit, in New York, rendered a decision upholding the order; subsequently,

the Fifth Circuit, in New Orleans, made a somewhat different ruling. We hope that these court of appeals decisions will be certified to the Supreme Court for review. It seems advisable to delay setting a hearing on the order delisting the four yellows pending the expected review of the previous matter by the Supreme Court.

Question.—

(3) What is the FDA position on H. R. 8945, which amends the Food, Drug, and Cosmetic Act to authorize a broad administrative listing of color additives permitted in food, as such or on a safe tolerance basis? Please answer this question from the standpoint of the following (among other) considerations: (a) This amendment is sponsored by the coal-tar color industry and one purpose of it is to place all competing colors under the administrative control now governing coal-tar colors alone. (b) If the Supreme Court decides that the administrator of this Act is now authorized to establish safe tolerances for coal-tar colors, then the basic need for this amendment has been removed as to coal-tar colors.

Answer.—

(3) We are familiar with H. R. 8945 which has been introduced in Congress proposing an amendment of the coal-tar color provisions of the Act. We are not in position to comment pending consideration of the bill by the Department.

Food Standards

Question.—

(1) To what extent has the Hale Amendment of the Food, Drug, and Cosmetic Act been administratively used to date? Please comment on its practical value as determined by this experience.

Answer.—

(1) Summary of Hale Amendment proceedings:

Fourteen Hale Amendment proposals have resulted in changes in the food standards. Some of these involved several foods—for example, the amendment permitting mold inhibitors in various cheeses.

Three Hale Amendment proposals resulted in rejection of the proposals. These were for muenster cheese, to delete the pasteurization requirement; for mozzarella cheese; and for partially creamed cottage cheese. Only the last went to a hearing.

Eleven Hale Amendment proposals are pending. Several of these must go to public hearings—for example, the canned tuna identity standard.

The procedure is working out, and in many cases it simplifies changes in standards.

Question.—

(2) What is the current administrative procedure for initially developing new food standards of identity, quality and fill of container, respectively, in general and from the standpoint of then consulting interested food manufacturers?

Answer.—

(2) Current administrative procedure:

The Hale Amendment was enacted April 15, 1954. This coincided with a period when FDA was working under reduced appropriations and we had quite limited resources available for work looking toward the development of proposals for new standards. As a consequence, we have had less experience under the Hale Amendment procedure with governmentally initiated proposals than we have had with industry-sponsored proposals.

Out of our more extensive earlier experiences, coupled with our limited recent experience under the Hale Amendment, we regard the following to be appropriate steps in the administrative procedure for initially developing new food standards:

(a) Identify the need for the standard. In many cases the need will be recognized from our enforcement activities. Food standards have as their object the promotion of honesty and fair dealing in the interest of consumers. Where we learn of practices inimical of these consumer interests—especially where such practices are widespread and require correction on an industry-wide basis—we consider whether a food standard should be established.

(b) Make field investigations. Our field districts are requested to have food and drug inspectors call on establishments and report the current practices. Sometimes these field investigations include distributors as well as producers. This is the step where we consult interested food manufacturers. Of course, we are pleased to have interested parties call at our field offices or to call on us here in Washington to give us the benefit of their views.

(c) Refer our findings to our food-standards committee—consisting of our four state and two federal food regulatory officials for whatever recommendation they wish to make to the Commissioner.

(d) Publish the proposed standard in the *Federal Register*.

Subsequent steps will not be different from those followed where the proposals are sponsored by industry.

Question.—

(3) What are the food standards of identity, quality and fill of container, respectively, which are now in the course of establishment or which are currently planned or contemplated?

Answer.—

(3) Pending standards actions:

All of the food standards which are now "in the works" are identity standards. Under the Hale Amendment, when an interested person petitions for the establishment or modification of a food standard and shows reasonable grounds in support thereof, the proposal is published in the *Federal Register*, and comments are invited. The next announcement in the *Federal Register* is the order ruling on the proposal and a notice that adversely affected parties have 30 days in which to file objections stating their grounds and requesting a public hearing. The following identity standards are now in the stage between the proposal and the order: Artificially sweetened canned fruits; prickly pear jelly; citrus-juice products—Frozen concentrate for lemonade, orange-juice products.

Identity standards for the following foods have proceeded beyond the "order" stage, and the hearings have not yet been held on the objections which were filed: canned tuna; enriched rice; cheeses—samsoe, ricotta, mozzarella, grated American cheese food.

One packer objected to the prune juice standard because it did not include honey as an optional ingredient. The hearing was held and extended time allowed for the filing of briefs. The order ruling on the issue raised by the objection has not yet been published.

As for planned or contemplated food standards, we have partly completed accumulating information on breaded shrimp.

Question.—

(4) To what extent are foods now sold as imitation products as a result of the Supreme Court's decision that a food may deviate from its identity standard if it is labeled an imitation product, as provided

by the Food, Drug, and Cosmetic Act? Please explain whether this imitation-labeling plan is increasingly used and whether it has resulted in consumer deception, in the case of foods retailed from duly labeled bulk packages?

Answer.—

(4) Imitation products:

In 1953, two years after the Supreme Court had ruled in the so-called *Imitation Jam* case, FDA conducted a limited market survey to obtain information on industry trends in the use of the imitation label on food products.

The reports revealed a large number of imitation jams and jellies, both in consumer-size packages and in large containers for institutional or trade use. All of these imitations contained less of the fruit required in the standard products and many deviated from the standards in other respects.

Imitation cheese products produced in substantial amounts were encountered in the survey. These products, labeled as imitation—such as "Imitation Pasteurized Process American Cheese"—contained less milk fat and more moisture than the standardized articles.

We also encountered a number of salad dressings labeled as imitation. For example, one labeled as "Hotel Special Imitation Salad Dressing" contained substantially less oil and egg yolk than was permitted by the standard for salad dressing.

While a standard for ice cream has not yet been promulgated, it is of interest that the survey showed that the production of products labeled as imitation ice cream or which purport to be ice cream was substantially on the increase.

The survey revealed many other imitations that are not particularly new and cannot be attributed to the *Imitation Jam* decision.

From this brief survey and from the labels reviewed by FDA since the survey, we cannot but conclude that there is increased use of the imitation label on products which, prior to the *Imitation Jam* decision, would have been held in violation as purporting to be standardized products and failing to comply with the standards.

We have not made surveys to obtain consumer views on the deceptiveness of imitation foods packaged in large containers for institutional use or trade use. However, with many millions of Americans

eating all or part of their meals in public eating places, consumers usually have no way of knowing whether they are being served an inferior product in place of the standardized or otherwise recognized article.

Question.—

(5) Does FDA now plan to recommend an amendment of the Food, Drug, and Cosmetic Act to reverse that decision?

Answer.—

(5) The Administration does not plan to recommend corrective legislation to the Eighty-fifth Congress.

Question.—

(6) Does FDA approve the suggested amendment of the Food, Drug, and Cosmetic Act, which confines an identity standard for a food to a definition of its basically essential composition and whereby a manufacturer can otherwise freely improve it subject to the Act's general prohibitions against the harmful adulteration and misbranding of any food? If not, why not?

Answer.—

(6) We do not agree that the food standards section of the law should be amended as suggested in the question because we think the amendment would undermine the fundamental purpose of food standards as presently established.

Question.—

(7) The identity standard for milk bread does not permit its enrichment. But various states require the enrichment of white flour used in bread, including milk bread. Consequently bakers complying with this state requirement for milk bread are thus prohibited from shipping it in interstate commerce. Has the FDA considered this conflict in law from the standpoint of amending the Food, Drug, and Cosmetic Act standard for milk bread to permit its enrichment required by state law?

Answer.—

(7) We have not ourselves planned to take the initiative toward amending the standards for milk bread. Bakers may propose amendments if they find need for them.

Investigational Shipments

Question.—

The "new drug" law of the Food, Drug, and Cosmetic Act authorizes the administrative exemption of such drugs from the regular drug-labeling requirements, where they are intended solely for investigational use and provided they are so labeled, as specified by regulation. Will FDA approve this exemption plan for investigational foods? If not, will FDA approve an amendment of the Act to sanction such plan?

Answer.—

Our philosophy on this question is reflected in paragraph (j) of Section 409 of H. R. 6747, the Department's chemical additive bill. That section states:

> The Secretary (1) shall promulgate regulations providing for exempting from the requirements of this section any chemical additive, and any food bearing or containing such additive, intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of such additive, and (2) may by regulation exempt any other chemical additive, or any food bearing or containing it, or both, when in his opinion such exemption is consistent with the public health.

Oral Vitamin Products

Question.—

Some products are sold for special dietary use, under the food part of the Food, Drug, and Cosmetic Act, whereas others are sold in compliance with the drug provisions of this Act. What is the law of the Act in that situation? Please review it in detail.

Answer.—

One method of determining whether or not a product is a drug is to consider its intended use. If the use is as a therapeutic agent in the treatment of disease, the product is a drug.

Section 403(j) recognizes the use of foods to supply vitamins, and such special dietary use requires prescribed labeling. If a vitamin preparation is intended solely for use for supplementing the ordinary diet, it is a food for special dietary use and its labeling must comply with the regulations under Section 403(j).

If the dosage in the recommended daily intake of one or more vitamins in a multivitamin preparation is many times the minimum daily requirement, its intended use is obviously as a drug and it must be labeled as such.

Trace Mineral Elements

Question.—

What so-called "trace mineral elements" does FDA now consider to be (1) essential in human nutrition, (2) harmless in reasonable amounts and (3) potentially harmful to health, respectively? Please discuss this situation in detail.

Answer.—

The term "trace elements" stems from the fact that some elements may be present in such small quantities that the amount cannot be expressed in units of weight, but their presence can be demonstrated by suitable tests, and may be said to be present in "mere traces." When these trace elements are considered from the standpoint of need in human nutrition, we speak of those that may be needed in quantities less than is required for iron.

Those for which a need has been established are copper and iodine. Manganese, zinc and cobalt have been shown to be essential for some forms of animal life, but evidence with respect to man is lacking.

There is some suggestive evidence that molybdenum and selenium may play an essential role as part of enzyme systems in animal metabolism. Fluorine, in spite of the favorable effect it has in preventing dental caries, has not been shown to be an essential element. The element cobalt needs special consideration. It is not an essential element for man unless it is combined in vitamin B_{12} or cobalamin.

In summary, copper and iodine are the trace minerals essential for man, and are harmless in ordinary intakes. Copper is probably harmful at ten or more times the ordinary intake; the harmful level of iodine has not been established, but probably exceeds 100 times the requirement.

Chemical Additives

Question.—

The Administration has said that there are about 150 chemical additives in food which have not been adequately tested for safety. What are the names of the additives in this class? Please comment on the scope and frequency of their use and the question of their potential danger.

Answer.—

Dealing with the second part of the question first: We do not have sufficient information on the uses of various chemical additives

to be able to make any satisfactory estimate as to the scope and frequency of their use. This is one of the difficulties confronting us in the assessment of the chemical-additives problem. It is probable that many of the uses of these substances currently employed by industry are without significant hazard. Contrariwise, it is altogether probable that uses or proposed uses of some substances will be found not to be safe when subjected to critical investigation.

It should be understood that any list of chemical additives is in a constant state of change. New substances are continually being developed and new uses proposed for older substances. Problems of the possible additive effects from the increasing use of many different food chemicals cannot be overlooked in our considerations of this matter.

Most of you are probably familiar with the publication issued in 1956 by the National Research Council-National Academy of Sciences on the use of chemical additives in food processing. It consists of a comprehensive listing of the chemicals for which the food protection committee of the NRC found evidence of use. Their listings group the chemicals as to usage: preservatives; antioxidants; sequestrants; surfactants; stabilizers and thickeners; bleaching and maturing agents; buffers, acids, alkalies; food colors; nonnutritive sweeteners; nutrient supplements; flavoring agents; miscellaneous (such as yeast foods and firming agents).

In a number of these categories, there are substances about which no adequate toxicological information is available and many others for which only limited data are available. In particular, sufficient information is not known as to the safety of some of the surfactants employed as emulsifiers. A large number of the flavoring agents fall in the category of additives for which toxicological data are lacking.

New Drugs

Question.—

What are the practical rules to be used in determining whether a drug is a "new drug" within the meaning of the Food, Drug, and Cosmetic Act?

Answer.—

The term "new drug" is defined in Section 201(p) of the Federal Food, Drug, and Cosmetic Act, briefly, as (1) any drug the composition of which is such that it is not generally recognized by qualified

experts as being safe for use under the conditions for which it is being offered in its labeling or (2) any drug which investigative studies have shown to be safe, but which has not been used to a material extent or for a material length of time. The term is further defined in Regulations 1.109 and 130.1(f); it is this that is used as a yardstick in making a determination of the new-drug status of a specific product.

A drug may be a new drug because, among other reasons: (1) It contains a substance which has not previously been used in therapeutics. This substance may be the active ingredient, a preservative, or a constituent of the vehicle, tablet coating, etc. (2) It is a new combination of old drugs in which a question of safety arises from the possibility of unknown synergistic effects, or it contains new proportions of old combinations of drugs to which the same questions of safety apply. (3) It is an old drug recommended for treating new diseases in which the effect of the drug on new pathologic conditions must be evaluated and the optimal dosage established. (4) It is an old drug recommended for use in a manner different from that known to be safe, such as by increased dosage, for longer periods of time or by a different route of administration (that is, by injection, in contrast to oral use, the safety of which has been previously established).

A new drug continues to be a new drug for a considerable period after its safety has been demonstrated by investigative studies. This period allows testing of the drug under marketing conditions in contrast to the carefully supervised conditions of investigation. The period of new-drug status varies with a number of factors such as the volume of distribution of the drug and, hence, experience with it; the incidence of adverse effects encountered; the complexity of its physiological action; the necessity for labeling revisions, and difficulty with manufacturing procedures, stability or assays.

Evaluating Performance

Question.—

What means does FDA use to evaluate and measure its performance in keeping its operations streamlined and efficient?

Answer.—

The allocation of manpower for the enforcement of the Act follows closely a pattern of approximately two thirds to food programs and one third to drug, device, cosmetic, and other obligations. Our avail-

able manpower is allocated by a system of commodity codes, of which there are 18 in the food area. Semiannually, each district receives a project chart allocating the inspection time for each commodity code. This provides the basis for district work plans. The project chart is developed from statistics of industry density, from review of our regulatory experience of prior years and from knowledge as to the degree of compliance which characterizes the industry. The percentage of available manpower to be devoted to a particular food group or commodity code—for example, bakery products—varies with the apparent need and is influenced by the emergence of new programs or particular problems in other current programs.

Appraisal of performance is an area which is constantly under study to improve methods and provide better management data. The FDA problem in this area is, in all likelihood, comparable to that of industry. At the completion of each year, a project analysis is prepared which summarizes the total time, establishment inspections, samples collected and examined, regulatory actions undertaken, and related operations. This is made possible by daily time and production reporting of each chemist and inspector in the field. Mark-sense cards, capable of machine processing, are used to simplify preparation and final sorting and tabulating. The completed project analysis provides a summary, by districts, of the significant activities and manpower utilization for each commodity area. It is intended to permit an over-all evaluation at headquarters and at the same time provide the district Chief with a means of comparing and evaluating the work of his own organization.

In the area of output per man in terms of work units, we are investigating criteria that will give useful information.

Safe Chemical Additive Uses

Question.—

Should not FDA now progressively announce the chemical additives it finds safe for use under the conditions of their intended use, defining these conditions?

Answer.—

What this question asks in effect is: "Shouldn't we begin to establish tolerances under Section 406(a) for permitted additive residues in food?" There are two conditions that must be met before we

can establish such a tolerance: (1) The necessity for using the chemical or the unavoidability of having it present must be established. (2) Evidence must be available to show that the proposed level of use is safe. It is our view that industry would have to supply evidence of necessity or unavoidability in addition to presenting evidence of safety before we are in a position to recognize any poisonous or deleterious additive. Thus far, no firm has established the necessity of using any chemical additive, other than pesticides on fresh fruits and vegetables.

Evaluating Toxicity of Additives

Question.—

(1) To what extent has FDA revised its methods for determining the safety of chemical additives since Dr. Arnold J. Lehman last discussed this subject in the FOOD DRUG COSMETIC LAW JOURNAL?

Answer.—

(1) The chronic-toxicity studies are carried out essentially as discussed in the JOURNAL. However, for suspected carcinogens, we are presently using two strains of rats and two strains of mice, and employing a larger number of animals at each feeding level and dogs which are kept under observation for seven years.

The effect of stress is also given serious consideration. At present, reproduction in rats is being investigated as one condition of stress. The effects of heat and cold are being explored.

Greater emphasis is being placed on the biochemical aspects of food additives.

Question.—

(2) What, in general, are the scientific studies of chemical additives now being made by FDA, through Dr. Lehman's division? There is a wide desire of the industry for all that Dr. Lehman can briefly say on this subject.

Answer.—

(2) We are presently engaged in studying the chronic toxicity of three FD & C dyes with emphasis on the carcinogenetic aspects. A number of flavoring agents are under study in a screening program. Several pesticides are currently under study for the determination of

their biochemical effects. In particular we are investigating FD & C Red No. 2; Greens Nos. 1 and 3; over 36 flavoring agents; the pesticides endrin, Diazinon, malathion, Dypterex, Trithion.

Nonnutritive Artificial Sweeteners

Assume: (1) A nonstandardized food or beverage is sold for general, and not special, purposes, and neither purports to be nor is represented for special dietary use. (2) It is properly labeled, including a correct ingredient list. (3) The name is not misleading. (4) It contains a nonnutritive artificial sweetener, included for the sole purpose of enhancing the sweetness of the product to the level required by the consumer, since adding additional amounts of the nutritive sweetener would impair the quality of the finished product.

Questions.—

Is special dietary labeling required?

Would the product be considered adulterated under Section 402(b)?

Answers.—

What the questioner desires evidently is a brief statement of FDA's views about the use of nonnutritive artificial sweeteners.

In the first place, the nonnutritive sweetener must be nontoxic.

In the second place, no nonnutritive sweetener is permitted in any confectionery.

The assumptions are that the entire question relates to a nonstandardized food which is legally labeled.

This reduces the question to proper labeling and possible adulteration of two classes of foods: (1) generally known foods and (2) specialty or proprietary foods.

If the food is one which would be expected to contain a nutritive sweetening agent and instead it contains a nonnutritive artificial sweetening agent, it should bear the labeling required by Section 403(j) for special dietary foods. This would naturally be an imitation of a known food and should be conspicuously labeled as such, as required by Section 403(j). In addition we believe that such foods should be segregated from ordinary foods at the retail level and any display material should emphasize the special dietary character of the food. The National Research Council has recommended that foods not contain both nutritive and nonnutritive sweeteners.

On the other hand, if the food is a specialty or proprietary item which would not be expected to contain a nutritive sweetener, it might be possible to offer it for sale under fully informative labeling for what it is and not necessarily as a special dietary food. This, of course, does not mean that such foods would comply with state laws.

The Administration would gladly comment on labeling for any product if furnished complete information regarding its formula. However, it is the responsibility of the distributor to determine the special dietary properties of his product.

Nonstandardized Food

Assume: (1) A nonstandardized food or beverage has one of several ingredients substituted for one which has previously been used. (2) The substituted ingredient is not harmful in any way. (3) It has equal or superior nutritive value. (4) The product is properly labeled, including listing of ingredients.

Questions.—

Would the product be considered adulterated under Section 402(b)?

Is the addition of the substituted ingredient, by itself, sufficient to make the product an "imitation" under Section 403(c)?

Answer.—

It is impossible to give an informative answer to this question without having more facts. If the questioner will supply details about the actual product involved and the problem that confronts him, we will be glad to comment.

Use of Color Instead of Egg

Assume: (1) A nonstandardized food contains egg yolk. (2) It is properly labeled, including an ingredient list. (3) It contains yellow color to enhance the color imparted by the egg yolk.

Question.—

Would the product be considered adulterated under Section 402(b)?

Answer.—

Yes.

A. J. AMOS, F. R. I. C., Discusses

Food, Food Science and the Food Group: A 25-Year Review

Dr. Amos, Retiring Chairman of the Food Group of the Society of Chemical Industry, Which Has Its Headquarters in London, Addressed the Annual General Meeting of That Group, Held on May 8 of Last Year. His Paper Is Reprinted from *Chemistry and Industry* for October 19, 1957

> **"Short views we take, nor see the lengths behind;**
> **But more advanced, behold with strange surprise**
> **New distant scenes of endless science arise."**

I HAVE CHOSEN these words, written over 200 years ago by Alexander Pope, as the text of my address tonight because I believe that in any sphere of human endeavor we can map more surely the road ahead if we occasionally look back over the path we have already traveled; experiences behind us should help to lessen mistakes in the future. It seemed to me that tonight was a particularly apposite time to pause and look back—to stay and "see the lengths behind"—because this is the silver jubilee year of the Food Group of the Society of Chemical Industry. What lessons can we learn and what guidance for the future can we gain from the march of events during the group's 25 years of existence? How has food improved and food science advanced during that period, and has the food group kept in the van of the march?

Those in our ranks who qualify as "young members," whose memories and experiences as food scientists go back to no more than a few years before the group's twenty-first birthday, may not realize how great have been the changes which we older members have seen during the lifetime of the group. Moreover, even those of us who can look back over more than 25 years of professional life are apt to forget how different were conditions when the group held its first annual general meeting. May I remind you of a few facts? In 1932—the year

the group came into being—it was reported that vitamin A was "apparently half a molecule of carotene to which had been joined two atoms of hydrogen and one of oxygen"; experiments were being carried out on the use of solid carbon dioxide in preserving perishable foodstuffs during transport; the molecular structure of vitamin C had not been established and the recommended international unit was 0.1 cc. of fresh lemon juice; the official standard for several types of milk included limits for plate counts; the isolation of vitamin B_1 was announced; flour cost 25*s*. per sack compared with 106*s*. today; and an editorial in *Chemistry and Industry* stated: We were privileged the other evening to make a tour of upwards of 20 miles of the main thoroughfares of south London to inspect the newest system of high-pressure gas lighting.

In the intervening years, science and technology have made great strides and it is partly due to progress in food science and technological advances in the food industry that the pattern of food consumption has altered. Today we are spending a significantly greater proportion of our total income on food, and this change in the consumer's budget remains when allowance is made for the effect of inflation. In 1955, over 32 per cent of the consumer's income was spent on food. This increase in proportionate expenditure on food arises from a change in the type and quality of foods consumed rather than in the quantity eaten. More expensive foods and foods of better quality are more frequently bought and, in particular, prepacked and processed foods which require less preparation by the housewife. Because very few foods are eaten in their natural form, food processing, preservation and presentation, which are responsible for the allocation of nearly one third of the consumer's income, constitute one of the most important of the nation's industries.

Appeal to Eye and Palate

The periodical consumption of a sufficiency of suitable food is essential for the continuance of life, but there is no reason why we should not make this necessary task an enjoyable one. Certainly, our liking for the delights of the table should not be so great that we overindulge, but it is to our advantage temperamentally and physiologically if we can look forward to, enjoy in the fulfilment, and remember with pleasure, each of the meals we take in our thrice-daily necessary task of providing our system with their nutritional requirements. Picture for yourself the temperamental and physiological difference, the difference in energy and zest for life, between Cassius with his

lean and hungry look, who attracted the comment "such men are dangerous," and A. P. Herbert's Mr. George Surbiton, who enters the breakfast room singing:

> O breakfast, O breakfast, the meal of my heart!
> Bring porridge, bring sausage, bring fish for a start,
> Bring kidneys, and mushrooms and partridges' legs,
> But let the foundation be bacon and eggs!

If, then, we should not only eat to live, but also love to eat, each of our foods—in addition to being nutritionally appropriate, clean and wholesome—should have good consumer appeal, that is, be attractive to the eye and to the palate. These attributes will do more than enhance the relish with which we partake of a food; they will stimulate our desire for it and, in so doing, increase the contribution which that food makes to our nutrition. The nutritional benefit we derive from a food is determined by its intrinsic nutritive value and the amount of it which we consume; a highly nutritious food will make little contribution to our over-all nutrition if we find it so lacking in appeal that we eat little of it, whereas a food of only moderate nutritive value which has good eye and palate appeal may rank high on the credit side of our nutritional balance sheet because it constitutes a major ingredient of our diet.

Improvement of Raw Material

Attractiveness to the eye and the palate should be attained by the application of good processing to good raw material; during the last quarter of a century, much has been done in the direction of improving food manufacturing plants and technique, and in the production and selection of the raw material. Researches in genetics, in animal and plant nutrition and in well-planned breeding trials have led to the production of new and improved varieties in both the animal and vegetable kingdoms. While attention has been paid to the resistance of the plant or animal to disease during the growing period—for this may have a marked bearing on the economics of production—a major object of the researches has been the development of raw material possessing those attributes which render it most suitable for its intended purpose. Examples that come to mind are the development of new strains of fruit possessing those properties particularly desired for quick freezing, canning or jam making; of new and improved strains of biscuit wheats and bread wheats; of improved malting barleys; of better bacon pigs; and of superior dairy herds. The intro-

duction of grading systems and of tests for maturity, condition and suitability for the proposed process has enabled the raw material to be so sorted that the processor can select what is best suited to his purpose. Illustrations are the use of the Tenderometer and other instruments in canning factories for grading vegetables and fruit on the basis of maturity and quality; the introduction of a price-determining grading system for bacon pigs; and the adoption of specifications for biscuit flours based on mechanical dough tests. The progress that has been made in production and subsequent selection means that the fruit and vegetable canner, the preserve maker, the flour miller, the maltster, the brewer, the bacon curer, the biscuit maker and the dairy farmer have an advantage over their confreres of 25 years ago in that the raw material from which they produce their finished food products is of higher and more consistent quality because much of it has been specially bred and selected for them.

Progress in Processing

Improvement in the quality of the raw material is only one step forward toward the production of better food; if the consumer is to reap the benefit of advances made in plant and animal genetics; in crop growing and harvesting; in stock breeding; in grading, testing and sorting; and in preprocessing preservation, then the methods and equipment used to convert the raw material into the finished product must enable the transition to be accomplished without serious impairment of the aesthetic qualities or the nutritional value of the food. The processing should, therefore, be efficient, but not severe enough to cause damage or loss of nutrients, and it should be completed without undue delay, while the equipment and the material from which it is constructed should make it easy to maintain hygienic conditions and to avoid contamination. Progress in these directions has proceeded concomitantly with the improvement in raw material, but—again—only a few examples must suffice. Worthy of note are the increased use of stainless steel; pneumatic conveying; high pressure sprays and foam-washing for the cleaning of vegetables; heat and chemical peeling of fruit and vegetables; high temperature-short time sterilization; mechanized heading and gutting of fish; and vacuum syruping and steam closure in the fruit cannery.

Packing and Wrapping

While good raw material and good processing are prime necessities in the production of a food of good quality, eye appeal is

influenced also by the manner in which a food is presented for sale. The past 25 years has seen a marked change in the direction of prepacking and wrapping; today, very many foods are presented in attractive containers or covers, which enhance sales appeal and also provides a means of introducing advertising matter at the point of consumption. In addition, this replacement of bulk deliveries to the retailer by separately packed purchasing units has reduced the amount of handling the food receives and, hence, has lessened the risk of contamination and has enabled transport and storage space to be utilized to better advantage. The consumer, too, has benefited by the change because the prepacked or wrapped foods are more immune to atmospheric spoilage and contamination from external sources both on retail premises and in the larder. This progressive trend toward attractive presentation in separate purchasing units has recently extended even to the sale of fruit and vegetables. It is a growing practice to present some vegetables cleaned and graded in a transparent wrapper and to display tomatoes and apples in plastic baskets.

Another noticeable trend in the food industry during the lifetime of the group has been the introduction of measures which save time and lessen labor for the housewife. Help in this direction commences with the retail trade in the self-help store, but the food manufacturers' contribution has been directed to lightening the task of the housewife in preparing meals in the home. An example that readily comes to mind is sliced bread. In a household where sandwich lunches are prepared daily, the use of ready-sliced loaves is sufficiently time- and labor-saving to ease considerably the housewife's early morning duties, but many other households also prefer the convenience of having the bread sliced for them by the baker. Another example in the cereal field is the introduction of quick-cooking oats, competition in this sphere having reached a stage at which a "porridge" can be prepared from one product merely by the addition of hot water. Meat pies—in tins—which can be served after a relatively short heating to cook the pastry, prepacked Christmas puddings, good-quality soups in powder form which can be prepared in a few minutes, cleaned and trimmed vegetables, and partially cooked rolls which require only a few minutes' baking are other examples of the food producers' efforts to render easier the burden of preparation of their wares. They have even gone so far in their efforts as to trespass on the holy ground of home cake-making. Developments in this sphere have aimed at providing the housewife with a prepacked mixture from which a good-quality cake

can be made by the addition of nothing but water. A complete premix of this nature contains, in addition to the flour, sugar and aerating chemicals, appropriate proportions of fat, dried milk and dried egg.

Food Hygiene

During the last 25 years much progress has been made in the control of the cleanliness of food. In the early days of the group's life, the extent to which hygiene and good housekeeping were practiced in the factory, in the warehouse and on retail premises was largely a matter of choice. The reputable producers and vendors of food were keenly aware of the need for cleanliness and protection against contamination, and took appropriate precautions, but there were others who were ignorant of, or disregarded, their responsibilities in these directions. Today there is a practical approach to the problem and in the Food and Drugs Act, 1955, there are embodied regulations, specially relating to hygiene, under which producers and purveyors of food can be penalized for acts or conditions which are potential, and not necessarily actual, causes of pollution.

Food and Nutrition

We can say, therefore, that the past 25 years have seen very definite advances in the provision of cleaner food of improved quality which is more attractively presented, and often in a form which calls for less preparation in the home. The progress which has been made in these directions by the food scientist and food technologist undoubtedly enables us to enjoy our food more; lessens the work of the housewife; and reduces wastage, but we must not forget that the primary function of food is to provide us with nutrition. If we eat more of a food because improvements in quality and processing enhance its attractiveness and appeal, we gain nutritionally, but we benefit even more if the food has also been improved as a source of nutrients. Progress has certainly been made in this direction; raw material of better quality and advances in processing have resulted in a higher initial nutrient content, on the one hand, and less loss during manufacture, on the other; in addition, the fortification of foods with synthetic nutrients has become a reality. Compulsory fortification began with margarine, the obligatory nutritive addenda being vitamins A and D. Much more recently, regulations were introduced which prescribed a nutritive standard for flour and which meant, in effect,

that all flour had to contain at least as much vitamin B_1 nicotinic acid and iron as does flour of 80 per cent extraction. Thus, the intake of iron and of vitamins A, D, B_1 and nicotinic acid which would result from a given consumption of long-extraction bread spread with butter is now obtainable from the same quantity of much preferred white bread spread, if desired, with the less expensive margarine. In addition, flour is also fortified with calcium.

Food Additives

Because the incorporation of nutrients in food—even the addition of chalk to flour—benefits the majority of consumers and probably harms none, very little objection is raised to the practice of food fortification. The addition of chemicals other than nutrients to foods, which is practiced for various purposes, has, however, been the subject of attack from various quarters, and an intensified campaign was initiated by the discovery that flour treated with nitrogen trichloride would give dogs running fits.

In the main, a food additive other than a nutrient is used for one of three purposes. It may function as a processing aid, as do flour improvers, since in their absence the task of the baker would be more difficult and the quality of the bread inferior; it may render the food more attractive to the consumer, as do colors, flour bleachers, flavors and crumb softeners, or it may prevent deterioration and wastage, as do those substances which inhibit bacterial spoilage, oxidative rancidity, rotting of fruit or staling of bread. In recent years, food scientists have been actively engaged in research on substances within each of these categories, and their investigations have been reflected, among other developments, in the substitution of chlorine dioxide for nitrogen trichloride as a flour improver, in the use of glycerol monostearate as a crumb softener, in the development of efficient antioxidants, in the use of polyoxyethylene monostearate as an anti-staling agent for bread, in the addition of sodium monoglutamate as a flavor intensifier and in the discovery of new sweetening agents. Research has not been confined to the discovery of new products or the improvement of old products capable of aiding processing, improving appearance or increasing storage life, but has extended to the fundamental chemistry and physics of the changes which the additives bring about and to the pharmacological and nutritional aspects of their presence in foodstuffs.

A situation was developing where, in the absence of official intervention, there might have been a widespread use of a multitude of

additives, some of which might have constituted a health hazard if ingested regularly over a long period of time. Some safeguard was provided by Section 1 of the Food and Drugs Act, 1955, but a more positive official direction was desirable. A subcommittee appointed to review the situation has recommended permitted lists—a logical approach—of antioxidants, bread ingredients and food colors. The soundness of the evidence on which some additives have been excluded from the permitted list has been criticized, but from the aspect of national health and well-being it is wise to err on the side of safety when any suspicion attaches to an additive until properly planned and extended tests have given it a clean bill of health. The adoption of permitted lists of additives will throw onto the food industry the onus of producing evidence of the harmlessness of any proposed new food additive; already, thought has been given to the establishment of an institution designed, equipped and staffed to undertake such research on behalf of food manufacturers.

New Methods of Food Preservation

Because of the growth of antagonism to the addition of "chemicals" to food, particular interest attaches to modern work on preservative methods which escape the stigma of chemical treatment. Within this category falls "cold sterilization," as it is called—that is, the sterilization of foods by means of ionizing radiations. The appropriate application to foodstuffs of hard or soft X rays or of cathode rays as sources of beta or gamma rays can destroy insects, food spoilage and pathogenic micro-organisms, as well as helminthic parasites, and also prevent sprouting of vegetables and delay ripening in fruits. Preservation by irradiation may, however, be of limited applicability because, unless low dosage levels are employed, the acceptability of the food may be impaired by the development of "irradiation odors" and the food may acquire a long-term toxicity, such as carcinogenicity. These possible objections to irradiation of food at high dose levels are under investigation but, should they be established, the use of radiations as a means of increasing the storage life of foodstuffs would not be ruled out of court; the joint use of low dose levels of radiations and of heat offer some promise, while sterilization of heat-sensitive packaging materials by irradiation might well be a fruitful line of research.

Another modern development in the preservation of foodstuffs is the use of antibiotics. This is not a practice which is permitted in Britain but it has been adopted in several countries, including Canada

and the United States. Examples are the addition of aureomycin or terramycin to poultry, of aureomycin to the ice used for packing fish, and of polymyxin to brewery yeast cultures. A possible danger in the use of antibiotics is a change in the spoilage pattern, resulting in a preferential suppression of those micro-organisms which are normally responsible for indications of poor bacteriological condition. And in any use of antibiotics there is a real risk of establishing a population of resistant micro-organisms.

Food Labeling

A modification of food presentation which has been introduced in the period under review is the declaration of ingredients and nutrient content. Regulations calling for a declaration on the container of the ingredients of a prepacked food came into being partly because of the necessary use of substitute foodstuffs during the war period. The practice of declaration of ingredients has much to commend it and it imposes no hardship upon the reputable manufacturer. Similarly, the enforced declaration of the amount of certain nutrients in a food when claims for the presence of those nutrients are made benefits the purchaser by protecting him against false or exaggerated claims, without restricting the activities of the honest manufacturer.

I have thus far attemped to review the changes and trends in the food industry during the 25 years the group has been in existence. Because of the time at my disposal and the scope of the subject I have been unable to do more than present to you a very cursory survey, but even this is sufficient to reveal the progress that has been made in the provision of cleaner food of declared composition and improved quality—and often of a higher nutritional status—which is more attractively presented, keeps longer and calls for less preparation in the home.

Progress in Food Science

Progress in food technology means progress in food science: New processing methods call for new control measures; the introduction of new additives requires new analytical techniques for their detection and determination; fortification with nutrients leads to refinement of biological methods of assay; and the narrowing of already existing standards and specifications makes for progress in instrumentation. Today, methods of analysis which were unknown as analytical tools when the group came into being are in widespread use in food laboratories. Problems which we older members solved 25 years ago only by

performing intricate and laborious analyses can now be elucidated rapidly by chromatography. During the same period the polarograph and the flame photometer have come into their own as valuable assets in those sections of the food laboratory called upon to make numerous routine determinations of specific elements. In 1932, the then known vitamins could be assayed biologically only by the use of animals or birds—an expensive and lengthy task—but since then we have progressed from cages to test tubes and now use bacteria, yeast and molds as our test organisms with a great saving of time and labor and, consequently of cost. The application of microbiological procedures extends to the determination of amino acids, and it is the older food chemist, who has known the day when the laborious and complicated Van Slyke technique was the only means of analyzing a protein hydrolysate, who appreciates the boon of now being able to determine quantitatively and reliably the constituents of a complex mixture of amino acids by the relatively simple and quick microbiological procedure. The phosphatase test has displaced the plate count in the routine testing of milk; adsorption indicators and complexones have permitted new analytical techniques to be developed; and radioactive tracer techniques have been used to good advantage in food research laboratories.

The progress which has been made in food quality, food technology and food science during the lifetime of the group can be gauged by reviewing the situation today against the background painted by the group's founder chairman 25 years ago. In 1932, Dr. Lampitt wrote: "Speaking generally, food industry today has next to no scientific control." How different is the situation today. The industry is very alive to not only the benefits of, but indeed the necessity for, scientific control; it is not uncommon for even small firms to maintain a simple scheme of control testing or to utilize the advisory services of research associations. Whether the supervising or advisory scientist be a member of the firm's personnel, one of the staff of a research association, or a private consultant, he does not restrict his attention to analyses of raw material and finished product, but pays particular attention to hygiene. Even before the introduction of the Food and Drugs Act, 1955, food chemists were alive to the importance of good housekeeping in the factory and did what they could to foster hygiene. No longer do they deserve the censure which Dr. Lampitt leveled at them in 1932 in the statement: "I find very little attention paid by chemists to the actual state of cleanliness of premises."

Speaking of flour in 1932, our first chairman said "a raw product of which very little fundamentally is known" and "the appeal to the loaf is still the only method of judging flour." As a result of the continuous studies of cereal problems that have been conducted since then, in which the research associations of the flour-milling and baking industries and scientists employed within or retained by the industries have played no small part, we now know a great deal about the fundamental chemistry of wheat flour and of the biochemistry and physics of dough. No longer is it essential to have recourse to a baking test in order to assess the suitability of a flour for its intended purpose. We have learned much about the action of improvers and the distribution of nutrients in the wheat grain; developments in technology which this progress in scientific knowledge has prompted have enabled the miller to enhance considerably the natural vitamin content of his flour without a concomitant deterioration in color and have enabled the baker—should he so desire—to produce bread of normal commercial quality from untreated flour.

Work of Food Group

What of the food group during the past quarter-century? Has it kept in the van of the march forward of food science and technology, and has it been of real service to its members and to the industry which they serve? A study of the syllabuses reveals how early in the history of a scientific or technological trend has the group discussed the subject at a meeting. As long ago as 1932 it held meetings on "Factory Cleanliness in the Food Industry" and "The Need for Standardization of Products Containing Added Vitamins"; two years later it discussed "Physiological Aspects of Additions to Foodstuffs"; in the current session it has discussed the possibility of using antibiotics and ionizing rays for preserving foodstuffs. In the years between the appearance of its first and its latest syllabus the group has cast its net wide; many papers have been presented on the production, the processing, the preservation, the presentation and the purity of food for human consumption, on food additives, on nutrition, on animal feeding stuffs, on food analyses and on the training of food technologists. Other papers have dealt with various aspects of individual foods; a quick glance at the annual programs shows that the commodities covered include cider, bread, cocoa, tea, meat, eggs, fish, fats, chocolate, potatoes, wine, fruits, yeast, butter, vegetables, sugar, flour, sweet confectionery, milk, cheese, honey, cream, bacon, soya and water. Some of these foods have been discussed on more than one occasion.

In the early days of the group's existence, a feature of each annual program was two meetings in the provinces with other groups or local sections. Succeeding committees have very wisely fostered this practice, and today our group does more for its provincial members than any other group of the society; in the 1956-1957 session it has held joint meetings in Dublin, Bristol, Birmingham, Edinburgh and Nottingham. Your present committee is in favor of giving members out of London an even greater opportunity to participate in the activities of the group; to this end it has arranged that the annual young members' meeting, about which I will say more in a moment, shall be held every other year in the provinces.

Cooperation with Other Bodies

Another feature of the group's activities has been joint meetings with bodies outside the parent society, and in the last year or two these have been augmented by collaboration with the newly formed Association of Public Analysts. There is much to be gained and nothing to be lost by such exchanges of views and discussions of problems between those who decide formulation and control quality as producers and those who supervise composition and quality on behalf of the consumer. At one time there was a tendency for some food manufacturers and some public analysts to consider themselves in opposing camps, in a state of undeclared war, but as time has passed each side has come to understand more the problems and difficulties of the other. Liaison between them through the activities of the group must ultimately be to the benefit of both the food industry and the consuming public.

That the reputation of the group stands high not alone in the parent society is evident from the occasions on which its assistance is sought by outside bodies. For many years, the Royal Sanitary Institute—now the Royal Society of Health—has invited the group to organize a session on food and nutrition at its annual health congress and has invited its chairman to be president of the session. This is the only session which is not organized by the Royal Society of Health, and it speaks well for the group that the request for collaboration has continued over a series of years.

Further evidence that the group has established itself as a body worthy to be consulted on matters appertaining to food science and food technology is the invitation which it received to nominate a repre-

sentative to the board of governors of the National College of Food Technology. More recently, the group was asked by The Food Law Institute of the United States to undertake jointly with the Society for Analytical Chemistry and the Association of Public Analysts the organization of a one-day conference in London in July during the visit of the American Bar Association.

The healthy growth of the group and the scope of its activities during its early years were reflected in the formation of two panels—the nutrition panel and the microbiological panel—by the time the group was eight years old. At that stage, the membership of the group had risen from an initial 197 to 345, but it has continued to rise, and has now reached more than 1,000. The work of administration has so increased that it became necessary last year to appoint an additional honorary secretary. It is a far cry from the group's first session when a program consisting of only seven meetings led to an entry in the minutes which read: "It was generally felt that the program for 1932-1933, though justified for a first session, was too heavy for an ordinary year." The program for the 1956-1957 session lists seven joint meetings within the society, a joint meeting with the Royal Society of Health, three ordinary meetings, a symposium, this annual general meeting, a young members' meeting, a summer meeting, the summer tour, and the *conversazione*—to say nothing of four nutrition panel meetings.

Activities Abroad and Past Services

Perhaps one of the happiest suggestions of the founder chairman during the second year of his office was a summer tour to Paris, Brussels and Amsterdam. Probably he little thought at the time that the summer tour would become a regular feature of the group's program and one which, I am sure, is the envy of other groups in the society. I would like to dispel any impression that these summer tours are in the nature of jamborees. I happen to hold the record, having participated in all but one of them, and I can assure you that they are indeed strenuous and fully meet the description applied when we visited France of being *voyages d'étude;* after one has visited two, and sometimes three, factories or laboratories each day for nearly a week; has climbed innumerable stairs because the party is too large for the lift; has passed from boiler houses to refrigerated stores; has sampled cheese and potted meats before lunch and chocolate, ice cream

and pumpernickel in the afternoon; and has imbibed such unusual liquids as milk and mineral water, one is almost in need of a week's convalescence.

The organization of a summer tour, which means arranging transport, accommodation and visits for nearly 50 members, is a task of considerable magnitude, but I am convinced that, arduous as it may be, it is a task well worth while. A summer tour provides participating members with an opportunity to broaden their technological experience, to acquaint themselves with analytical and control measures used in other countries, to see research projects in progress and, above all, to make personal acquaintance with scientists overseas. In offering this service to our members, we are indirectly serving the food industry, which must ultimately benefit from the knowledge and experience which food chemists can gain on a summer tour. But the value of these tours—which, except for a break during the war years, have continued since 1934—lies not alone in the benefit derived from them by the participants and the industry which employs them; they have resulted in the food group's becoming known throughout most of the countries in Europe as a live and keen scientific group of able food scientists. The reputation and regard which the group has attracted overseas must undoubtedly react to the advantage of the parent society. It is a record to be proud of that, during its existence, the group has made its name known, and established lasting contacts, in Belgium, France, Holland, Germany, Denmark, Eire, Switzerland, Norway, Italy and Austria.

The fine record which the group can show for its first 25 years of existence—a record of service to its members, to the food industry and to food science and technology—could not have been achieved were it not for the ready willingness of a long list of its members to devote a great deal of time and thought to the administration of the group's affairs. To these members who have served, and served so well, as honorary officers and members of committee during the past 25 years the group owes a debt of gratitude. The second annual report of the group referred to "the zeal with which every member of the Committee has carried out the various detailed duties that have been placed in his care" and the continued expansion of the group's membership and activities is proof, if proof be needed, that succeeding committees and honorary officers have not fallen short of the standard of keenness and conscientiousness set by the pioneers of the group.

Future Opportunities

But what of the future—the next 25 years? The opportunities for continued growth and progress are golden; science and technology are advancing rapidly, and the number of potential new members is ever increasing. If we are to take advantage of the tide, we must have available enthusiastic members who will be willing and able eventually to take over the helm. To this end we must not slacken, but rather must intensify, our efforts to keep and to stimulate the interest of the younger members in the affairs of the group. A start has been made in this direction through the medium of an annual young members' meeting, when younger chemists still in the early days of their careers are encouraged to talk about their own work—be it a description of a novel piece of apparatus, a report of a new analytical technique or a discussion of the significance of collected analytical data. It is not enough, however, that we should endeavor to get these younger members interested in the group—we must make it clear that the group is interested in them. We older members, and officers and committeemen in particular, should take steps to make them feel welcome at meetings and to ease any diffidence that stems from the differential in age and experience. Let us insure that we know who they are and from whence they come and that we do not remain merely names to them. The young members of today are potential committeemen of tomorrow; the more we encourage and help them, the more sure can we be that, at its golden jubilee, the group will have no less pride of achievement than it has tonight. It may have greater cause for pride 25 years hence because as, in the words of Pope, "new distant scenes of endless science arise," there will be scope for expansion of its activities and of the services which it provides. Into the hands of those that follow us, therefore, we give this opportunity, believing with Lowell that:

> New times demand new measures and new men;
> The world advances, and in time outgrows
> The laws that in our fathers' day were best,
> And, doubtless, after us, some purer scheme
> Will be shaped out by wiser men than we.

[The End]

Some Landmarks

ALONG THE DEVELOPMENT OF THE FOOD LAW AND ITS ADMINISTRATION SINCE WORLD WAR II

By SAMUEL A. McCAIN

The General Counsel, Corn Products Refining Company, New York City, Spoke at the 1958 Meeting, Section on Food, Drug and Cosmetic Law, New York State Bar Association, on January 29

General Background Prior to End of World War II

The food, drug and cosmetic law was enacted in 1938. Its administrative development had a good start, though the Federal Food, Drug, and Cosmetic Act was not fully effective until 1940. Standards hearings were held and procedures were developed, and standards were promulgated in the case of ten groups of products: 1940—(1) tomato products, (2) egg products, (3) certain canned fruits and (4) an extensive list of canned vegetables; 1941—(1) cream, (2) condensed, evaporated and dried milks, (3) jams, jellies and preserves, (4) certain cheeses, (5) oleomargarine and (6) wheat flour.

Because of the provisions of the new Act, the enforcement activities of the Food and Drug Administration were greatly expanded. The detail of these developments is of much interest, and can be reviewed in the reports of the Federal Security Administrator for the years in question.

The food, drug and cosmetic law provided by its terms that the Administrator could grant exemptions from the labeling provisions pending the issuance of standards. Exemptions were issued covering a number of products, for some of which standards of identity have since been issued. In the following instances, however, the labeling exemption or policy to the same effect has continued, but will be terminated in the present year: malted milk; unmixed canned fruits, including canned berries (except those for which standards of identity

have been issued), provided for having less than 20 briques packing media; olives in brine; extracts (lemon, orange and vanilla); and nonalcoholic carbonated beverages.

During World War II, the Food and Drug Administration of necessity concentrated (1) on the demands of the war effort, particularly the armed services, for their technical and administrative help and (2) on policing and enforcement—made difficult by all the new imports, substitute products and shortages which accompanied the war, as well as the huge production effort made by the food industry and agriculture.

Standards-making activity during the war period was confined to amendments of previous standards and to some additional cheese standards on which hearings had been held, also to certain fill-of-container provisions. Of necessity, a great deal of this work was delayed until after the war.

With the end of the war, the Food and Drug Administration, the food industry and the bar all took a renewed, and, with seven years' experience under their belts, a more informed look at the backlog of the regulations and standards to be developed in the coming years.

Formation of New York State Bar Association Section

With this background in mind, it was apparent that much could be done to carry out the educational spirit indicated in Section 705 of the Act. Two far-seeing members of the New York State Bar Association—Lewis C. Ryan, who was then president, and Charles Wesley Dunn, one of the leaders of the bar, particularly in the food field—decided that a food, drug and cosmetic law section of this association would be a constructive step. Such a section would furnish (1) a meeting ground for lawyers with a common interest in the field, (2) a forum for discussion of legal and related problems in connection with the law governing the largest industry in the United States and (3) a means of self-education of the bar and others interested, through authoritative official presentation of decisions and policies, both administrative and legal, in the field.

Mr. Dunn, with characteristic vigor, took time by the forelock and gathered together a number of interested lawyers. The section was established on July 19, 1945, with 27 charter members, and immediately proved a success, together with its brother section, the antitrust law section, which was formed at about the same time.

Food Drug Cosmetic Law Journal

The next year—1946—saw the first publication, again under the leadership of Mr. Dunn, of the FOOD DRUG COSMETIC LAW JOURNAL, in March. This started as a quarterly; since 1950, it has been a monthly. The JOURNAL is published in association with The Food Law Institute. This is the authoritative publication in the field and is widely referred to not only in court decisions, but in industrial, technical and legal publications of all kinds.

Formation of American Bar Association Division

In 1947, also under the leadership of Mr. Dunn, the formation of a division of the American Bar Association—around the nucleus of mutual members of this association and the American Bar Association, already gathered together in this section—was actively discussed. The year 1948 saw the formation of the new food, drug and cosmetic law group in the Administrative Law Section of the American Bar Association.

The American Bar meetings in the summer and the meetings of this section in the winter furnished a series of meetings, properly spaced in time, for a continuing discussion of continuing and new problems. Subsequently, the group became a division of the Corporation, Banking and Business Law Section of the American Bar Association because of greater community of interest with that section.

New York State Bar Association Section and Legislation

The group in this association and in the American Bar Association admirably complement each other not only in timing, but in the fact that while the American Bar Association offers a wider forum and has more members, the smaller group in this association can act more quickly in the matter of emergency problems and Congressional appearances than is possible in the larger organization. To take two instances:

(1) An emergency arose when the Supreme Court largely nullified the factory-inspection provisions of the Food, Drug, and Cosmetic Act. This section could act quickly through resolutions and present its views to Congress through its chairman, giving Congress the considered opinion of the food and drug bar in a very short time.

(2) A second instance arose when the close of the war saw the commencement of a new series of long standards hearings, some of which heavily taxed the resources not only of the government personnel involved, but of the informed bar in the field, as well as technical

and executive industrial personnel. Need I mention the mayonnaise and salad-dressing hearings, the bread hearings, and the frozen fruit and ice cream hearings, to mention only a few. Suffice it to say we all learned in the next five years that standards hearings could be long-drawn out, expensive and heavy consumers of time, taxing to the full the FDA, the bar and industry.

When it became obvious to all that some means must be found to eliminate the unnecessary work, time and expense involved in standards hearings, this section was in a position to act immediately by resolution and testimony before Congress to push the legislation which became the highly successful Hale Act.

The Food Law Institute, Inc.

I now come to what I consider one of the most important, if not *the* most important, landmark to which this paper is addressed. I refer to The Food Law Institute, which was incorporated in 1949 and which is now taken for granted by most of the food and drug bar and by the food industry, without too widespread a realization of all that is being accomplished, the success of the institute to date, and its possibilities for the future. The institute, when it was formed, appealed to my imagination as having great possibilities; I have followed its progress with interest, growing excitement and a good deal of gratification to these final months of its ninth year.

The institute, a nonprofit organization, was incorporated in 1949, with William Robbins, then of General Foods Corporation, as chairman of its board, and with Mr. Dunn as its president and moving spirit. It was originally financed by 12 founder members, all leaders in the food field, and supported by a strong group of advisory lawyers, among others the late John Prescott, Bradshaw Mintener, James Best, Edwin Harding and E. B. Kixmiller. As a part of its development, the advisory lawyers' group was further strengthened by such public representation as Robert Curran, William Goodrich, and Vincent Kleinfeld, as well as a large number of well-known law professors and industry lawyers, many of whom you see here today in this bar group.

The two fields of the institute—as originally laid out—were, first, *education* and, second, *research* in the food law.

Education Program.—The education program, in several parts, is a big conception of college and public education. Its international phases represent the broadest approach to the subjects.

Education in Colleges.—The first step in the program was the setting up of a chair of food law at New York University, and the endowment of a number of fellowships for the study of food law, with a view to encouraging not only the study of the food law at the college and law school level, but its study at the graduate level. Mr. Dunn has served as the professor holding this chair, without compensation. William Goodrich and Vincent Kleinfeld have regularly lectured at New York University since the inception of the program. Numerous other members of this section have lectured on subjects of interest in which they were involved. Executives in the food industry have lectured on other relevant subjects.

There were five fellowships a year at New York University to start with and, more recently, four (chiefly because funds sufficient to cover more fellowships and the other expanding programs were not sufficient). The total of the fellowships to date is over 40. From these 40 we now have an attorney in the Food and Drug Administration; Thomas W. Christopher, associate dean of Emory University Law School, who has just been appointed to the executive committee of the Association of American Law Schools, which is a great honor; two deputy state attorneys general; two Assistant United States Attorneys; and a number of professors and lecturers on the food law. Food Law Institute fellows have also joined outstanding companies in the food, drug and cosmetic field—Swift & Co.; Schering Corporation; Charles Pfizer & Company, Inc.; Ames Company, Inc.; and Hercules Powder Company—as well as law firms in general practice.

During these nine years, as a result of, and in conjunction with, the New York University program, similar programs including study at the graduate level were established at George Washington Law School and Southern California Law School. Regular courses in the food law are now taught at Stanford Law School, Emory Law School and Northwestern Law School.

Mr. Dunn has given one or more lectures at the following universities: Harvard University—business school, law school and public-health school; Yale University; McGill University (Montreal, Canada); Northwestern University—medical school and law school; University of California Law School (Berkeley); Hastings College of Law, University of California (San Francisco); Duke University Law School; University of Illinois Law School; University of Texas Law School; Tulane University Law School; Vanderbilt University Law

School; University of Washington Law School (Seattle); University of Miami Law School; Emory University Law School; and University of Virginia Law School.

As a result of all these activities and the availability of books published by the institute for textbooks (which will be referred to later), the food law is gradually becoming a part of the curricula of a large number of law schools and technical schools—if not as separate courses, then as part of more-general courses, as at Harvard, Yale and technical colleges. Food law is conveniently made a part of courses on commercial law, administrative law, business law, and health and sanitation, to name only a few.

The Food Law Institute has reports of food law instruction at the following schools: University of Alabama, University of Kansas City, University of Miami (Florida), University of Minnesota, University of North Carolina, Indiana University, University of Houston, University of New Mexico, University of Wisconsin, John Marshall Law School (Chicago) and University of Missouri.

The Food Law Institute probably offers the most constructive approach to obtaining good and as-uniform-as-possible state and local laws and regulations through education of college students in law schools and technical schools, to know what is needed in the field from the standpoints of uniformity, desirable provisions and standards of enforcement.

Public Education.—A very effective portion of the education program has been the sponsorship by The Food Law Institute of public conferences and meetings on the food and drug law or addresses at appropriate public meetings. The program is designed to promote national and international understanding (and, incidentally, uniformity) in the field of food law. A partial listing of these meetings and addresses follows:

1950—(1) a government luncheon in London, given by the United Kingdom Ministry of Food in honor of the institute; (2) an address at a government ceremony in Ottawa, organized by the Canadian Department of National Health and Welfare to commemorate the seventy-fifth anniversary of the Canadian Food and Drugs Act; (3) an industry dinner in London, given by leading English food manufacturers in honor of the institute.

1951—an address at the conference of the Association of Food and Drug Officials of the United States, in Philadelphia.

1952—public meetings at San Francisco and New Orleans—these Food Law Institute public meetings were organized to include leading federal and state enforcement officials, faculty members of leading law schools, executives of the food industry and leaders of the bar.

1953—a Food Law Institute public meeting, similarly organized, in Atlanta.

1954—(1) an address by Mr. Dunn at a Los Angeles public meeting at the time of a meeting of food technologists; (2) a lecture tour by Ernst Abramson, M. D., director of the National Institute of Health, Sweden.

1955—a lecture tour by Mr. Dunn at Scandinavian and German universities.

1956—a fiftieth-anniversary meeting in Washington, commemorative of the enactment of the 1906 food and drug law.

1957—(1) meeting—sponsored by The Food Law Institute, the Food Group of the Society of Chemical Industry, the Society of Analytical Chemistry and the Association of Public Analysts—in London, on July 26, at the time of the American Bar Association meeting there—this meeting discussed the problems relating to food additives on an international level; (2) an address by Mr. Dunn at the Inter-American Bar Association meeting in Buenos Aires in November, recommending the establishment of a new food, drug and cosmetic law section in that association (as a result of this meeting, the governing council of the Inter-American Bar Association and its executive committee have organized a section with the following officers: chairman—Dr. Jorge E. O'Farrell, of Buenos Aires, senior partner in the major law firm of Marval & O'Farrell, which is counsel for leading United States food and drug manufacturers doing business in Argentina; vice chairmen—Mr. Dunn, as chairman of the ABA division on this law and as president of FLI, Victor C. Folsom, of New York City, foreign counsel for Sterling Drug, Inc., and Dr. Noe Azevedo, of São Paulo, a distinguished Brazilian lawyer, who is counsel for leading United States food and drug manufacturers doing business in that country; and executive secretary—Dr. Enrique E. Bledel, of Buenos Aires, local counsel for a major United States beverage manufacturer, who is a graduate of the NYU Inter-American Law Institute. The Food Law Institute is also translating a model food code drafted by Dr. Carlos A. Grau, of Buenos Aires. This code will be presented at a chemical congress in Mexico City next year for general approval,

and it is hoped will become a standard food law in the Latin-American countries); (3) a meeting in Washington, sponsored by The Food Law Institute, at which the leading officials of the Food and Drug Administration outlined their philosophy, organization and plans, as well as programs and policies currently being carried out, attended by leading members of the food industry and leading food lawyers, with—following the presentation of papers—a question-and-answer period developing the subjects presented (I regard this meeting as the beginning of the most important single program of public education in the United States in the field of the food law).

1960—The British Ministry of Food has formally approved an international meeting to be held in London in 1960, to commemorate the one-hundredth anniversary of the first national food law in the English-speaking world (the meeting is now being organized by leading scientific organizations in Great Britain, with whom The Food Law Institute is cooperating).

Research Program.—The research program is outstanding in producing the "Food Law Institute Series" of books which serve as textbooks in college and public-education programs, of immense value to the members of this section as practitioners and to officials and scientists connected with the administration of the law.

The series includes, to date: *Federal Food, Drug and Cosmetic Law Administrative Reports, 1907-1949;* Kleinfeld and Dunn, *Federal Food, Drug, and Cosmetic Act, Judicial and Administrative Record, 1938-1949* and *Federal Food, Drug, and Cosmetic Act, Judicial and Administrative Record, 1949-1950* and *Federal Food, Drug, and Cosmetic Act, Judicial and Administrative Record, 1951-1952;* Curran, *Canada's Food and Drug Laws;* Christopher and Dunn, *Special Federal Food and Drug Laws—Annotated;* Vernon and Depew, *General State Food and Drug Laws—Annotated;* Dierson and Dunn, *Product Liability Cases;* and a reprint of a 91-page study of the food, drug and cosmetic law, done at Harvard Law School and originally published in the *Harvard Law Review.*

To this list may be added two books now ready for publication—a fourth Kleinfeld and Dunn book on the judicial, legislative and administrative record under the Act to cover the years from 1952 to 1957 and a book on the constitutionality of the food law by Professor Christopher.

Other books on special state food laws and Latin-American, British Commonwealth, European and other international food compilations are being actively developed.

Report of Citizens Advisory Committee on the Food and Drug Administration

On July 7, 1955, the Citizens Advisory Committee on the Food and Drug Administration, headed by G. Cullen Thomas, made its report to Oveta Culp Hobby, then Secretary of the Department of Health, Education, and Welfare. The committee consisted of 14 citizens, selected for their interest in civic affairs and broad knowledge of consumer and industry problems, to evaluate the adequacy of enforcement of the federal food and drug laws.

Bradshaw Mintener, at that time Assistant Secretary of the Department, deserves no small share of the credit for the organization of the committee. The members of the committee were Catherine Dennis, president, American Home Economics Association, Raleigh, North Carolina; Grace Drexler Nicholas, executive director, General Federation of Women's Clubs, Washington, D. C.; Patrick T. Stone, United States District Judge, Wausau, Wisconsin; Frank W. Abrams, former chairman of board, Standard Oil Company, New York City; Harry Dowling, M. D., professor of medicine, University of Illinois, Chicago; Charles Wesley Dunn, president, The Food Law Institute, New York City; Robert A. Hardt, vice president, Hoffman-LaRoche, Inc., Nutley, New Jersey; Leonard A. Maynard, M. D., director, School of Nutrition, Cornell University, Ithaca, New York; Lee W. Minton, president, Glass Bottle Blowers Union, AFL, Philadelphia; Charles Franklin Poe, professor of food and drug chemistry and public health, and dean, College of Pharmacy, University of Colorado, Boulder; Herbert N. Riley, executive vice president, H. J. Heinz Company, Pittsburgh; Walter F. Silbersack, president, American Home Products Company, New York City; and H. Gregory Thomas, president, Chanel, Inc., New York City.

The major conclusions and recommendations were:

(1) The Administration then had insufficient funds, staff and facilities to meet its essential responsibility; this serious deficiency should be corrected by increased appropriations for FDA. The required increase was between a threefold and a fourfold one, made within a period of five to ten years and as fast as it can be absorbed from an efficient organizational standpoint; the first increase should be from 10 to 20 per cent over the 1956 appropriation. The increase each year should be based on an evaluation of FDA's record in the past year and its need in the next year; the Secretary may well appoint

a small *ad hoc* citizens advisory committee each year, to aid in this evaluation.

(2) The Administration should have its own modern building in Washington, to house and consolidate its headquarters organization and facilities under the most effective operating conditions.

(3) The Administration should improve its affirmative educational administration of the Federal Food, Drug, and Cosmetic Act, as distinguished from and in avoidance of its negative court enforcement of this Act; it should establish a Division of Educational Operations to do so. This Act is best administered on a voluntary compliance basis, and such compliance is best secured by FDA educational action for it. The Administration should reinstate its valuable publication of trade correspondence on this Act, to further its educational administration.

(4) The committee made 140 specific recommendations in its report. This report is a thorough and complete study of FDA as a whole, and its operations and programs. The report appears in the FOOD DRUG COSMETIC LAW JOURNAL for August, 1955.

Food and Drug Administration

There is no question but what FDA itself and the expansion of its powers under the Federal, Food, Drug, and Cosmetic Act of 1938 is the landmark which dominates all others in this field; a knowledge of that fact is assumed on the part of those to whom this paper is directed. This is not intended to be in any sense an assay of the operations of the Administration and, in discussing the development of the food law and its administration since the war, I should like first to mention the fact that we have been extremely fortunate in having broad-gauged administrators, of proper training, ability and—most needed of all—wisdom. The naming of Commissioners Paul Dunbar, Charles Crawford and George Larrick in itself will give to those of you who are here today the picture from your own knowledge of how a monument has been built by these men—stone by stone.

I wish to reflect the benefits of a recently undertaken publicity program which was conceived by Commissioner Larrick and which, as I mentioned above, was responsible for a meeting of some 100 of the leaders of the food industry and their lawyers and food and drug officials under the cosponsorship of the Food and Drug Administration and The Food Law Institute.

This program in itself is of far-reaching importance, and we hope for a continuation of these meetings, at least annually, in the future. Commissioner Larrick brought out at this meeting that of the 140 recommendations made by the citizens advisory committee, the Food and Drug Administration has acted substantially on 56 of these and it has made progress on 75 others.

Generally, this further progress is directly related to the increases scheduled by the committee in the appropriations of the Administration. It is the consensus of all concerned that this is a wonderful showing.

There is one other recent development that I think is highly important to the members of this section here today. The citizens committee recommended the resumption of the publication of the so-called trade correspondence, or its equivalent, by FDA. Within the past few months, the Administration has carried out this recommendation in its informal statements of general policy or interpretation, which are now published in the *Federal Register* and which are also reproduced in the legal bulletins of the Grocery Manufacturers of America. Needless to say, these bulletins are going to be of great usefulness to the members of the bar in connection with interpretation of the law, since they give the Administration's views on many phases of the Act.

Proposed Legislation

Flexible Standards.—To my recollection and that of a number of you here today, flexible, rather than recipe-type, standards have been discussed by members of this section over a period of some ten years.

The citizens advisory committee, in its report to the Secretary of Health, Education, and Welfare on June 30, 1955, included the following important recommendation (recommendation (5) in "Section 5-A: Food Programs" in its list of recommendations, at 10 FOOD DRUG COSMETIC LAW JOURNAL 525 (August, 1955)):

> The FDA should: . . .
>
> (5) Provide flexibility in food standards to permit of change for the improvement of quality or value, or the introduction of new varieties or forms.

For this purpose, new legislation is necessary to provide for the new type of standard. The legislation should amend the food, drug and cosmetic law to provide for food standards fixing only those ingredients necessary to safeguard identity and economic integrity.

Proposals to this effect by Michael F. Markel, of Washington, D. C., have been discussed in a series of articles appearing in the monthly magazine *Food Processing* for June-November, 1957.

You will note that a number of leaders in the food industry and a number of members of this section approve the proposals in principle. You will also note that letters in favor of these proposals have been sent to Senators and Congressmen in Washington.

I am not going to discuss the proposals in any further detail. I do want to say, however, that on their face they are highly constructive and, in the form of legislation, would represent a major development toward progress and modernization. I think the time has come for the members of this section to do some active work to accomplish these objectives.

Food Additives.—A paper on food law landmarks would be incomplete without some reference to food-additives legislation, which has been the subject of so much discussion and writing since 1950. I do not intend to add one word to the discussion of this legislation, but at the same time I would like to set forth a few facts to contradict some of the scare headlines that appear whenever the subject is discussed, as it may be at this session of Congress.

A substantial part of our food supply consists of branded foods, in packages, which are nationally advertised. These are the staples on the grocery-store shelf.

If you represented a supplier of ingredients to food manufacturers as I do, you would know that none of these manufacturers adds an ingredient to his product without exhaustive tests, both technical and analytical, as well as consumer-acceptance and marketing tests, irrespective of the merits. Why is this?

I asked the package sales manager and the advertising manager of my principal client to estimate how much of a capital expenditure would be involved in placing an easily marketed product on most of the grocery-store shelves in the United States. The answer was at least $5 million, and probably two or three times that amount.

On the same authority, in the 1920's, the number of items on the grocery-store shelf averaged around 500; today, the average number of items is around 5,000. Because of the terrific competition for the golden foot of shelf space, for every new branded product that is successful a number fail, and such new product must knock off the shelf an

established old-timer. Each brand must maintain a reputation as untarnished as that of Caesar's wife; if sales slow up, it comes off the shelf and off the market. Millions of dollars will be required to repair the damage.

I just don't believe that fly-by-nights have the means to stand this kind of competition; even if they did, self-interest would make them walk by day as slowly and carefully as did their competitors.

Unintentional additives to perishables such as fruits and vegetables have now been covered, so far as safety is concerned, by the pesticide amendment. The leading semiperishables—bread, processed dairy products and meat products—are subject to rigid standards.

The items mentioned above comprise practically all of our basic food supply.

I sincerely hope that any discussion of food-additive legislation can be approached in an objective way in Congress without any scare headline, by products totally lacking justification in fact, to cause public concern as to the safety of the Nation's food supply. **[The End]**

CONVICTION OF PHYSICIAN FOR VIOLATION OF SECTION 503(b)(1) AFFIRMED

In a recent decision, the United States Court of Appeals for the Fifth Circuit affirmed the conviction of a physician for the violation of the provision of the Federal Food, Drug, and Cosmetic Act that prohibits the dispensing of potentially harmful drugs—transported in interstate commerce—without a prescription. The case was on appeal from a decision of the United States District Court for the Northern District of Texas.

The court of appeals opinion held that the evidence fully warranted the jury's finding that the physician had violated Section 503(b)(1) by selling without a prescription, to two federal agents, three separate lots of dextro-amphetamine hydrochlorine tablets that had been shipped in interstate commerce. The contention that the act did not apply to physicians was discredited, for the "Supreme Court has on several occasions held that the purpose of the legislation is the protection of the people from dangerous products which are shipped in interstate commerce." A broad construction of the term "prescription" would not include a sale of potentially harmful drugs by a doctor to two strangers not examined by him and with whom he had not in any manner established a physician-patient relationship.

The court pointed out that the language of the statute, considered alone, "is certainly broad enough to make criminal what was done here." The appellant had argued that although the language is broad enough to include physicians, the statute must be interpreted differently.—Reported in CCH Food Drug Cosmetic Law Reports ¶ 7426 (January 16, 1958).

By MARION A. HOY

SOME DEFECTS IN OUR DRUG, AND COSMETIC

THERE ARE A NUMBER of defects in our Federal Food, Drug, and Cosmetic Act, but in the interest of space I shall discuss only two of them in this article. The first one involves the power of the federal government, acting through the federal Food and Drug Administration, to defeat a food processor financially even though the latter proves himself to be right in our federal courts. The second deals with what I believe to be a spurious interpretation of a given provision of the Federal Food, Drug, and Cosmetic Act by the Food and Drug Administration, under which interpretation the government has consistently seized admittedly good merchandise which happened to be in a shipment with other merchandise which was bad, even though the latter constituted but a small part of the shipment. I shall deal with the latter problem first.

21 USCA Section 334(d) . . . provides that:

> . . . after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter under the supervision of an officer or employee duly designated by the Secretary . . . .

The government's brief in a file covering four consolidated cases —Nos. 11544-11547 (1956), in the United States Court of Appeals for the Seventh Circuit—at page 54 contains the following statement:

FEDERAL FOOD, ACT

The Author—A Member of the Law Firm of Duday & Hoy, of Oak Park, Illinois, Suggests Remedies for Situations Where (1) the Government Has Power to Seize Admittedly Good Merchandise Shipped with Other Merchandise Which Is Questionable or (2) the Government Can Defeat a Food Processor Financially Even Though He Wins His Case

It is our position that "the article" which is subject to seizure and condemnation refers to the entire shipment of a food and not to any subdivision thereof. This proposition is evident from an analysis of the language and purpose of the Statute and its legislative history and has consistently been so interpreted by the courts.

Because of this position, the United States of America, acting through the federal Food and Drug Administration, assigned as error a holding by a United States district court which condemned only four codes of canned tomato paste found to be adulterated and refused to condemn the remaining codes, in the same shipment, which were found to be good.

A code is spoken of as all the cans bearing a given embossed marking, or code, on the cover end of the container. This marking usually consists of a combination of figures and letters, which serves to identify the product within the can and the time when the can was packed. In the four consolidated cases referred to above, there was a different code for each two-hour run during the 24-hour day. By noting the embossed code on any can, a person can tell the day, and

the two-hour period within the day, that a particular can was packed. One reason, if not the essential reason, for coding cans is that in the event of a bad run all the cans packed during this run can be segregated from the others, and the canner can thereby avoid the necessity of having to destroy good merchandise which otherwise could not be segregated from the bad. In a shipment of any size there will likely be cans bearing many different codes.

Interpretation of "the Article" by Courts

Contrary to the government's contention, the courts have not consistently interpreted the words "the article" mentioned in Section 334(d) of the Food, Drug, and Cosmetic Act as meaning the entire shipment; in cases in which the courts have been able to identify and segregate the adulterated "article" from the remainder of the seized lot, they have done so.[1] Despite these rulings by the courts, however, FDA persists in seizing all the good codes which happen to be in the same shipment with other codes that are bad.

In a case tried in Chicago in April, 1953, involving 20 codes of No. 2 cans of whole tomatoes,[2] the government admitted that 16 of the codes were good but, in line with its interpretation of "the article," seized the entire shipment. The question of segregating the codes did not come up in this case, however, as the claimant proved that all 20 of the codes were good. Had the government seized only the four codes which it contended were bad, there would have been no trial in this instance, for the canner would not have gone to trial to recover only four codes. But, because of the spurious interpretation of the words "the article" by FDA, the canner was faced with the alternative of having his entire shipment condemned or going to trial. He chose the latter.

When the FDA man who had ordered the seizure was on the stand, one question put to him on cross-examination was something like this: "Why did you seize any of those 16 admittedly good codes?" His answer was: "Because they were in bad company."

Suppose that instead of 20 codes there had been 200 in this shipment, of which only four were bad, would the government have done any differently? Like the 16, would not the 196 have been "in bad company"? When one starts to reach out beyond the merchandise

[1] *U. S. v. 1,950 Cases . . . Ventura Farms Brand Fordhook Lima Beans* (DC Ill., 1949); *U. S. v. 351 Cases . . . Canned Peas, Etc.* (DC Tex., 1950).

[2] *U. S. v. 558 Cases of Iona Tomatoes*, CCH Food Drug Cosmetic Law Reports ¶ 7260 (DC Ill., 1953).

that is actually bad and to seize admittedly good merchandise that happens to be associated in any manner with the bad, where is he going to stop?

Suggestion for Reasonable Definition

It seems to me that the only fair and reasonable interpretation to give to the word "article" is to define it as the smallest ascertainable unit which includes merchandise which is subject to condemnation. If only four codes are found to be bad, why seize 16 others which would not have been seized had the four not been found to be bad? How can anyone with logic, reason or justice say that because four codes are bad, 16 others must be seized and destroyed? This practice is not only unfair to the canner, but it results in an economic loss of good merchandise, which affects all of us.

The seized "article" is "to be destroyed or brought into compliance with the provisions of this Act." In passing this provision, I do not believe that it was the intention of Congress to destroy good food. If the food is good, as in the case of the 16 codes, there is nothing to be "brought into compliance." It seems only reasonable to me that the obvious meaning of the word "article," as intended by Congress, is that it should include only those units which are not in compliance with the Act, and which must either "be destroyed or brought into compliance." If 16 codes are admittedly good and would not have been seized if four other codes in the same shipment had not been found to be adulterated, certainly those 16 codes are not a part of the article "to be destroyed or brought into compliance." But apparently the meaning of this word "article" is going to have to be spelled out by Congress.

Another Question of Congressional Intent

Another solution would be to amend the Act to provide that, in any shipment of canned food which contains more than one code, before any code can be seized because of alleged adulteration of the product, samples of the code must first be examined for the alleged adulterant, and only those codes be seized in which the adulterant is found to be present in excess of any prescribed or recognized tolerance for the adulterant in the given product, and that FDA shall not withhold from the channels of trade any code which, in and of itself, is not subject to seizure. I can think of no more illogical reason for seizing a given code than that some other code happens to be bad. I do not believe that Congress ever intended anything so absurd.

Perhaps this is the place to mention another defect in the Act which was pointed out in a recent decision of the United States Court of Appeals for the Seventh Circuit. Except for the presence of decomposed tomato tissue, which is evidenced in the finished product by the presence therein of mold filaments, there are no announced or official tolerances for filth, such as Drosophila eggs and maggots, and worm and insect fragments, some of which are in nearly every can of some of our most widely consumed products.

On a product for which no tolerance for a given adulterant has been established, the FDA has contended that it can seize that product if it contains any quantity of the given adulterant under Section 334 (a)(3) of the Act, which provides:

> A food shall be deemed to be adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.

U. S. v. 1,500 Cases . . . Tomato Paste

Because of this provision, one Assistant United States Attorney once said to me: "All I have to prove is one peanut in a carload and you're licked." A United States court of appeals recognized this fact when it stated:

> A scientist with a microscope could find filthy, putrid, and decomposed substances in almost any canned food we eat.[3]

Further, in the same opinion, the court stated:

> . . . without imposing some limitation, the Pure Food and Drug Administration would be at liberty to seize this or any other food it chose to seize.[4]

One paragraph from this decision is highly significant on this point; in order not to distort its meaning, I shall set it out in its entirety:

> Despite our limitations as a court and the fact that Section 342(a)(3), 21 U. S. C. A., does not give us any power to limit the inescapable force of the words, "if it consists in whole or in part of any filthy, putrid, or decomposed substance," we do not think that Congress intended to let the acts of the agency under this subsection go completely without limitation. In Section 346, 21 U. S. C. A., Congress directed that the administrator provide tolerances for amounts of poisonous or deleterious substances that cannot be avoided and are not injurious to health. It would not be reasonable to think that Congress would direct the administrator to set tolerances for the allowance of safe amounts of *poisons* in food and then declare that the presence of small amounts of filth, etc., which would admittedly have no effect upon health "adulterates" food and justifies its seizure. We believe that if the fact that almost all food contains some filthy, putrid, and decomposed substances had been called to the attention of Congress, that body would have directed the administrator to provide reasonable and acceptable tolerances for these substances just as it did in the case of poisons.

[3] *U. S. v. 1,500 Cases . . . Tomato Paste* CCH Food Drug Cosmetic Law Reports ¶ 7324, 236 F. (2d) 208, 210.

[4] Case cited at footnote 3, at p. 211.

Now that this omission in the Act has been called to the attention of Congress by our courts, surely Congress will take the action necessary to correct this defect.

Counting Cost of Victory

The other question I want to discuss is the power of FDA to defeat a canner financially even though the canner proves to the satisfaction of our courts that his product is good.

Between the time that the canner's shipment is intercepted by FDA and the time formal seizure action is taken, two to four weeks may elapse. If formal seizure action is taken, my experience has been that close to a year will elapse before the trial of the case; the preparation and entering of the findings of fact, conclusions of law and order of judgment; and the settling of the various posttrial motions which invariably arise. This will throw the canner into the next canning season. Now if the canner should win and the government should appeal, it will be another year before the case is heard in the United States Court of Appeals, its opinion filed and the various motions settled. This places the canner in the second canning season following the season in which the litigated merchandise was packed. Most food processors use a more corrosive product, such as tomato paste, within 18 months from the time it is packed. To be sure, this gives them a margin of safety, but take two years from the storage life of this product and that margin of safety is pretty well gone.

After all this has been completed and the merchandise has finally been released to the canner, if he is lucky he finds a buyer for it, but only at a price considerably lower than the original contract price. As every canner knows, when the more acid products are held in cans for an extended period of time, sufficient hydrogen gas develops inside the cans to dissipate the vacuum therein, thereby resulting in what is known in the industry as, first, "hydrogen springers," and, after a little more gas has developed, "hydrogen swells." As long as the can is not perforated, however, the contents are perfectly good. But a person who is not familiar with hydrogen springers and hydrogen swells will naturally assume that a swelled can is spoiled, and its contents of no further value. I have in mind just such a case, where the canner found a buyer for his merchandise which had been released after it had been tied up for two years in litigation; shortly after a shipment of this two-year old merchandise arrived at the warehouse of the consignee, an FDA inspector paid a visit to the warehouse, noticed a few swells

in the shipment, and told the warehouseman that if those swells were not destroyed by the time he returned, which was to be a few days later, he, the inspector, was going to seize the entire shipment. A single FDA inspector cannot, of course, seize anything himself, but he can cause a prospective buyer to shy away from buying what he otherwise would purchase and use to good advantage.

In a talk before a group at the annual convention of the National Canners Association on February 22, 1953, in Chicago, one of the men high in FDA made the following statement:

> If the correction sometimes seems at the time to be harsher than the manufacturer thinks necessary, it is to be remembered that all actions are subject to trial in the courts and that the safeguards established for the manufacturer's protection are those of our Constitution and the laws of Congress.[5]

It is true that the canner has access to the courts if he feels that he has been unfairly treated, but for what purpose? Since the government is not required to post an appeal bond—as are other appellant litigants—it has little to lose in dragging a canner through the federal courts even when it knows that its chances of winning are virtually nil. When FDA seizes a canner's product, it in effect says to him:

> You might as well go along with us and not contest our seizure of your merchandise, because if you contest it and win, we will appeal. Before you ever get the merchandise released to you, it will have deteriorated in quality to a point where it will be worthless. In addition, you will have to pay the cost of storing the product during all that time.

To a canner who has spent years building a good reputation in the industry and, up to this point, has an unblemished record which he is anxious to maintain at almost any cost, the expense of litigating such a case may be worth while even though he would be far better off economically to let the seizure go uncontested. One large canner, after just such an experience, said to me: "I guess it's worth something to be able to prove you were right." But a small operator who is struggling to meet his next payroll and who can hardly afford the loss of his merchandise and still keep going can not afford to add to that loss the cost of litigation. So he lets the seizure go uncontested, even though he has ample evidence with which to win the case in court, only hoping that FDA does not make another seizure of his merchandise before he can get back on his feet financially.

I have seen this happen: The Administration seized a large shipment of canned merchandise and, after two weeks of litigation in the

[5] From address by John L. Harvey, Associate Commissioner of the Food and Drug Administration, Federal Security Agency, at the session on quality protection and food regulation of the National Canners Association, at Chicago, Illinois, February 22, 1953.

trial court—with the expense of bringing in expert witnesses from three widely separated states—the merchandise was found to be good and was released to the canner; the government appealed, and a United States court of appeals affirmed the judgment of the trial court; then when the canner shipped other cartons of the very same codes, which both the district court and the court of appeals had found to be good, to a consignee in a distant state, they were intercepted by FDA and held up for several days, to the point where the consignee was about ready to cancel the order and make a similar purchase elsewhere. The canner asked the Chief of the FDA office in his district: "When are you fellows going to stop harassing us?" The answer was: "This is just routine checking."

I cannot reconcile any of the actions which I have described with the third basic principle of the Act, which is:

> It must impose on honest industrial enterprise no hardship which is unnecessary or unjustified in the public interest.[6]

I do not believe that any of the procedures which I have described were contemplated by Congress when this Act was passed, or safeguards would have been taken to prevent them.

Uncontrolled power is always dangerous. The power of FDA to deprive a man of his property until it becomes worthless and then to say, in effect, to him "all right, Mr. Canner, you win, but what have you got? only a hollow victory," is wholly inconsistent with the basic principles of the Act and with two statements made by President Eisenhower on his radio and television broadcast on the evening of November 5, 1956, which were: "We believe that Government must have a heart as well as a head." "The purpose of Government is to serve; never to dominate."

It would probably be useless to attempt to upset so long-established a principle as the one exempting the government from posting an appeal bond to protect the appellee-canner in the event the appellant-government fails to reverse the trial court; but there is a simple way by which the canners can be protected against these hollow victories. The Act now provides as follows:

> When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.[7]

It would take only a simple amendment to the Act to provide:

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[6] Report of Senate committee, S. Rept. 152, 75th Cong., March 8, 1937.

[7] 21 USCA Sec. 334(e).

When *no* decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, *including provable damages,* shall be *assessed against the government* in favor of the person, if any, intervening as claimant of the article.

If the courts were given the power to assess damages against the government in favor of the canner, in the event the government fails to sustain its charges, this, I believe, would be the most practical deterrent against FDA's starting unwarranted seizures.

I recall that after one seizure action was tried and lost by the government, one of the FDA men remarked: "That case should never have gone to trial." But the fact is it did go to trial, and for two years the canner's merchandise was held off the market, during which time it not only deteriorated in value, but the canner was put to the expense of defending a highly technical lawsuit requiring the testimony of three expert witnesses from three different states. Had FDA known in advance that in the event it lost that case, any damages which the canner suffered because of its action would be paid from its appropriations, I am quite sure that there would have been no seizure. But since it would cost the government nothing in the way of storage charges, loss of value in the product or expense of defending the action, why not take a chance? It is the canner who will pay! Pay he did, even though he won the case.

I do not need to describe or enumerate the serious consequences which could result from growing abuse of this kind of power. I can see no argument against requiring the government to reimburse a canner for damages which he has suffered because of legal action wrongfully brought against him by FDA. Such an amendment as I have suggested would accomplish this end, and would be in keeping with the basic principles of the Act, with President Eisenhower's statements, and with the American sense of justice and fair play.

[The End]

• POULTRY REGULATIONS PROMULGATED •

On February 5, 1958, regulations which apply to the inspection of poultry and poultry products in interstate or foreign commerce and in designated major consuming areas were promulgated, pursuant to the authority contained in the Poultry Products Inspection Act. The regulations will become mandatory on January 1 of next year.—Reported in CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 743.10 (February 14, 1958).

BERNARD L. OSER REPORTS ON

The Functional Value of Food Additives

Dr. Oser Notes: If the Per-Se Doctrine Is to Be Replaced by an Alternative Better Geared to Technological Advances, Special Circumstances Where Weight May Be Given to Functional Value Must Be Delineated More Clearly. He Addressed the January 29 New York State Bar Meeting . . .

BILLS DESIGNED to improve regulatory control of food additives have been incubating in the laboratories of Congress for the past five years. So far the only law to hatch from this process has been the Miller Amendment, covering the use of pesticides. Failure to produce a corresponding law with respect to intentional food additives may be attributed to both environmental and genetic factors. From the environmental standpoint it could be said that much light has been cast on the need for such legislation, but perhaps not enough heat has been turned on. However, the major difficulty has been genetic, that is, unsuccessful cross-fertilization of germinal ideas within the regulated industries or between them and the government.

It is to one of these controversial issues that I propose to address myself today—namely, whether functional value shall be assessed by the regulatory agency in considering the introduction of any new food additive. I foresee a real danger that industry's reaction of *no pasaran* to these proposals may lead to further delay in enacting a federal amendment with the consequent threat of nonuniform state and local legislation.

There is no doubt that food additives are intended to serve some useful purpose. Every bill now before Congress defines additives in terms of intended use. The voices of the health officials, the medical professions and the consumer have been raised repeatedly against the purposeless addition of any nonnutritive substance to foods. To suggest that this does not coincide with the view of responsible industry

Fabian Bachrach

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is to build a straw man. Food producers and processors have, in fact, invited closer regulatory control over useful food additives. The question with which we are here concerned revolves around whether this control shall be limited to the issue of safety or shall include also an evaluation of usefulness.

Without entering into a semantic discussion of the subtle distinctions between such terms as "utility" and "functional value," let us examine how various agencies have expressed the concept that food additives must be useful. The Food Protection Committee of the National Research Council and the American Public Health Association have adopted the principle: "A decision to use an intentional additive in foods should be based on the assurance (a) that it will be safe, and (b) that it will benefit the consumer." [1] The Joint FAO/WHO Expert Committee on Food Additives has taken a similar position in its report discussing the "circumstances in which there is technological justification for the use of acceptable food additives *to the advantage of the consumer.*" [2] (Italics supplied.) Spokesmen for the Food and Drug Administration have expressed their views on this subject several times during the past year. At the Congressional subcommittee hearing last year, Commissioner George P. Larrick testified: "We think they (food additives) should be permitted only when there is some definite benefit to the producer or consumer to justify the risk involved." [3]

[1] *Principles and Procedures for Evaluating the Safety of Intentional Chemical Additives in Foods* (Food Protection Committee, National Research Council, November, 1954); resolution of the American Public Health Association, November 7, 1957.

[2] *General Principles Governing the Uses of Food Additives* (Report of the Joint FAO/WHO Expert Committee on Food Additives, Rome, Italy, December, 1956).

[3] Hearings before the Subcommittee on Health and Science, Committee on Interstate and Foreign Commerce, House of Representatives, 84th Cong., 2d Sess., 1956.

This extension of the allowable benefit to the producer was repeated by William W. Goodrich, General Counsel for the Food and Drug Administration, when he stated: "Public opinion will be satisfied only by a rational justification based on considerations of food technology or consumer benefit coupled with assurance of safety of the proposed use." [4] He went on to interpret consumer benefit as including:

> . . . a use which benefits him directly in terms of product improvement or food convenience, or indirectly in terms of improvement in food processing, storage, packing, or other steps in moving the food from its raw state to the dinner table.

The view that technological advantage is included in the broad concept of consumer benefit was also expressed by Winton B. Rankin, assistant to the Commissioner, in a recent address before the Manufacturing Chemists Association.[5]

Description of Justifiable Uses for Food Additives

Probably the most extensive description of justifiable uses for food additives is contained in the FAO/WHO report cited above. Included are (1) maintenance of nutritional quality, such as by the use of antioxidants; (2) enhancement of keeping quality or stability, with resulting reduction in food wastage, through the use of antioxidants, antimicrobial agents, inert gases, meat cures, etc.; (3) enhancement of attractiveness of foods by means of coloring and flavoring agents, emulsifiers, stabilizers, thickeners, clarifiers, and bleaching agents (that appeal to the eye as well as the palate is not a mere whim of the food producer is recognized by all nutritionists, since proteins, vitamins and minerals serve no purpose unless eaten); (4) providing essential aids in food processing (agents which function in this capacity include acids, alkalis, buffers, sequestrants, and various other types of chemicals). (These and similar acceptable uses are also described in Publication 398 of the food protection committee, entitled *The Use of Chemical Additives in Food Processing.*)

It is noteworthy that useful additives may accrue not only to the direct benefit of the individual consumer, but indirectly to the benefit of the public generally, by conservation or enhancement of the food supply. Moreover, enhancement of the nutritive value by means of an additive—be it a protective agent or a nutrient per se (such as a

[4] Goodrich, William W., "The Rational Use of Chemicals in Food," 12 *Food Drug Cosmetic Law Journal* 535 (September, 1957).

[5] "Incidental Additives," 13 *Food Drug Cosmetic Law Journal* 7 (presented before the Manufacturing Chemists Association, December 2, 1957, at Washington, D. C.).

vitamin or amino acid)—should be considered in terms of the food itself, not in terms of the diet as a whole. Whether or not such an additive is desirable from the standpoint of the nutritional needs of the population should be determined under other administrative authority and not be confused with the issue of the safety of food additives.

FAO/WHO Report re Situations Where Food Additives Should Not Be Used

Highly significant is the emphasis placed by the FAO/WHO report on situations in which food additives should not be used. These include uses which disguise faulty or careless processing methods; which encourage unhygienic conditions of handling; which result in deception of the consumer; which cause substantial loss of nutritive value; or, finally, "when the desired effect can be obtained by good manufacturing practices *which are economically feasible.*" (Italics supplied.)

Citation of the situations enumerated by the FAO/WHO committee in which food additives should not be used would be incomplete without mention of the fact that existing provisions of the federal law prohibiting adulteration and misbranding of foods provide ample protection against deception, filth, and depreciation of nutritive or economic value. It is not from this point of view that the consideration of functional value of food additives needs to be justified. The reference to good manufacturing practice recalls one of the objections raised to granting of administrative authority to pass upon functional values —namely, that control over manufacture is beyond the scope of a public-health measure so long as protection against adulteration and misbranding is assured. A good illustration of a situation that might arise is to be found in the testimony of Commissioner Larrick concerning the possible use of formaldehyde in milk. Despite the fact that a harmless amount of this substance can function as a highly efficient preservative, its use would be prohibited on the ground that departure from "good manufacturing practice"—the use of refrigeration, pasteurization, sterilization, etc.— should not be permitted. Were safety under conditions of use the only criterion, it seems unlikely that this use of formaldehyde could be prohibited in the case of milk.

Good Manufacturing Practice—Role in Safety Evaluation

The argument that consideration of functional value would be an intrusion of the government into control of technological practice overlooks the fact that the Federal Food, Drug, and Cosmetic Act gives the administrator authority to consider what constitutes good manufacturing practice, in relation to the presence of added poisonous or deleterious substances (Section 406(a)). Similar authority is exercised quite extensively in the promulgation of definitions and standards of identity of foods and, directly or indirectly, through factory inspection. If what constitutes good manufacturing practice can be given weight in situations concerning sanitation or "honesty and fair dealing," it seems not unreasonable that it may deserve attention in safety evaluations.

Since the Administration bill (H. R. 6747) contains practically all of the features to which industry witnesses have taken exception, let us examine how it takes functional value into account. In the first place, a "chemical additive," by definition, must be intended to preserve or alter food or be used "for any other purpose in producing, manufacturing, packing, transporting or holding food." (The definitions in all other bills contain a similar provision, except H. R. 8112 (Representative Miller), which describes use as "the intentional addition . . . for the purpose of imparting a desired quality to the food.") H. R. 6747 goes on to require not only a statement of the conditions of the proposed use (without which a decision as to safety under conditions of use would hardly be possible), but "all relevant data bearing on the functional value" of the additive. This is for the purpose of a later section which provides that the regulation permitting the additive shall not issue unless, among other things, the administrative agency is satisfied that the "proposed use has functional value." An exception to this provision is made "if he (the Secretary) finds that such additive is not a poisonous or deleterious substance."

FDA Attitude Concerning Functional Value

From what has already been said, it seems reasonable to expect that the Food and Drug Administration intends to construe functional value broadly to comprehend, in effect, any use which enhances the nutritive value, stability, acceptability or economy of food; aids in its production or technology; and does not encourage unsanitary handling. The Administration has professed its willingness to depart from the

present "necessity rule" as applied to poisons per se and to adopt the principle of safety under conditions of use, provided the additive is useful. However, the limitation of consideration of functional value to "poisonous or deleterious" additives provides no basis, other than the per-se doctrine, for ascertaining whether or not a substance is exempt from such consideration.

Past experience tells us that very few additives, old or new, could escape being classified as poisonous or deleterious by the per-se yardsick. If toxocological data obtained at a dosage level deliberately set high enough to induce an adverse response were to be used as the basis for defining a poison, practically all substances would fall into this category. But if the new approach to food additives is designed to replace this impractical per-se doctrine with an alternative better geared to modern technological advancement, it will be necessary to delineate more clearly the special circumstances under which weight may be given to functional value. If these circumstances cannot be specified in the language of the statute, they should at least be specified in the legislative history of the proposed revision of the law and not left to administrative or judicial interpretation.

Some Aspects of Safety Evaluation Explored

For a full appreciation of the role of functional value in assessing the permissive use of food additives, it may be profitable to explore, a bit, some aspects of safety evaluation. As is often the case in discussions of this subject, we must remind ourselves that all things are relative; safety, necessity and value, whether functional or otherwise, are terms which have no meaning in the absolute sense. In a paper published in 1953 in the FOOD DRUG COSMETIC LAW JOURNAL, I elaborated on the thesis that poisons do not exist in a vacuum.[6] Similarly, "safety" and "harmlessness" are relative, regardless of how "reasonably certain" we may be of judgments derived from human experience or animal experiments. If we acknowledge that safety to all persons under all conditions cannot be established with absolute certainty, it must be admitted that some residue of uncertainty remains. To minimize it, it is customary in the practical application of toxicological data to allow a "margin of safety." This is, strictly speaking, a margin for uncertainty; its magnitude is dependent on many factors. It pre-

[6] Oser, Bernard L., "Can a Poison Exist in a Vacuum?" 8 *Food Drug Cosmetic Law Journal* 693 (November, 1953).

sumably takes care of differences in susceptibility between species and strains of animals and for variations in human response due to age, disease, dietary habits or physiological stresses. Safety evaluations must take into account the nature of adverse effects induced by excessive dosage and particularly whether these are irreversible or cumulative. Fortunately, most food additives are intrinsically provided with brakes or warning signals, in the sense that undesirable effects in flavor, appearance or texture, or technological difficulties in processing guard against their excessive use. In such cases, and especially when their toxicity as judged by animal tests is of a low order, it is not necessary to establish maximum limits or tolerances. On the other hand, where sufficient built-in protection does not exist and the toxicological evidence justifies it, a maximum limit must be set on the use of the additive, the level being in the "safe" range, but no greater than that needed to do the job. Implicit in such cases is the possibility that amounts above the tolerance may approach, if not enter, the hazardous zone.

In view of the existence of a residual risk, however small, the Food and Drug Administration in its bill has claimed the prerogative of weighing this risk against the advantage to the producer or consumer. The exception, where the "additive is not a poisonous or deleterious substance," is couched in language which has proved so vague and impractical under the present law that it should, in my opinion, be replaced with a more realistic criterion. It is suggested that functional value should be a proper consideration in a safety evaluation only when the nature of the additive and the toxicity data are such as to require a tolerance limit on its use. Through this approach, the rejection of a proposed use would be based not on alleged lack of utility, but rather on the paramount issue of insufficient safety. This would apply only to additives where the degree of safety under conditions of use required that quantitative limits be established. Any intended use, even if safe, which constituted adulteration or misbranding could be nipped in the bud by warning the petitioner to this effect without confusing the issue with the safety of the food additive. Disputes concerning safety under conditions of use could be more readily resolved by experts or by the courts than can questions of functional value involving subjective or esthetic considerations, consumer preferences, and the like.

Need for Specific Definition by FDA

The Food and Drug Administration has agreed to "support legislation that permits even poisonous chemicals to be used at apparently safe levels, provided that in such cases the chemical serves some function that warrants taking the minimal margin of risk." If FDA were to go a step further and define its terms more specifically, I think the present roadblock would be removed. In short, what are needed at this point are:

(1) A comprehensive statement of acceptable functional values which might serve as the basis for regulations for the administration of a food-additives amendment. The FAO/WHO report could well be considered as a pattern for such a statement.

(2) A substitute for the per-se terminology in H. R. 6747 whereby substances "not poisonous or deleterious" are exempted from consideration of functional value. I submit that the latter should be limited only to such substances as require the establishment of maximum tolerances.

(3) A clear understanding that rejection of a proposed food additive would not be based merely on its alleged lack of functional value, but on considerations related to safety for use under conditions of use.

May I conclude by suggesting somewhat belatedly, a better title for this paper: "The Futility of Feuding over Utility." **[The End]**

ACQUISITIONS OF STOCK AND ASSETS— DRIED FOOD SEASONINGS

A food processor and retailer has been charged by the Federal Trade Commission with illegally acquiring a large manufacturer of dried food seasonings. Specifically, it was alleged that the acquisition may lessen competition substantially or tend to create a monopoly in the Nation as a whole, or in various parts of it, since this food processor can use its purchasing power to coerce suppliers to buy dried food seasonings from its acquired division by withdrawing or threatening to withdraw its patronage. Such coercion would increase the already-dominant position of the division in the industry.

The complaint notes that the processor's net sales from July 1, 1950, to June 30, 1951, were less than $175 million and rose to more than $268 million for the period July 1, 1955-June 30, 1956. (Issued December 18, 1957; released January 10, 1958.)—CCH TRADE REGULATION REPORTS ¶ 26,942.

CHRISTOPHER

COMMENTS

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Narcotics—Self-Incrimination.—A 1956 statute requires citizens who use, or are addicted to the use of, narcotic drugs (except a sick person under a doctor's care) or who have been convicted of a violation of a narcotic law—the penalty for which is a possible sentence of more than one year—to register before leaving or entering the United States.[1] In a recent case, the question of self-incrimination was raised, and the court held for the government.[2]

A person who does not wish to register may refrain from leaving the country. Registration here is, thus, different from compulsory testimony before a grand jury. Also, registration does not necessarily imply law-breaking. The statute of limitations may have run or the person may secure his narcotics directly from another person.

The situation is somewhat like that of the gambling tax statute. Under that law, a gambler in Washington, D. C., must pay a tax (register) even though gambling is a crime in the District of Columbia. In upholding this statute, the Supreme Court wrote:

> The only compulsion under the Act is that requiring the decision which would-be gamblers must take at the threshold. They may have to give up gambling, but there is no constitutional right to gamble. If they elect to wager, though it be unlawful, they must pay the tax.[3]

Another interesting aspect of the registration statute is that intent is not necessary for a violation. Normally, criminal statutes do require intent. But it is well settled that Congress (or the legislature) may dispense with this requirement when it feels it necessary to do so. Since about 1850, courts have upheld such statutes. Generally, the statute will be one in which intent is difficult to prove, and so convic-

[1] 70 Stat. 574 (1956), 18 USC Sec. 1407 (Supp. IV, 1957).

[2] *U. S. v. Eramdjian* (DC Calif., October 7, 1957).

[3] *Lewis v. U. S.*, 348 U. S. 419, 422-423 (1955).

tions would be hard to get. In such cases, Congress weighs the right of the accused against the public need for enforcement, and decides in favor of the latter.[4] Of such a statute, Chief Justice Taft wrote:

> While the general rule at common law was that the *scienter* was a necessary element . . . and this was followed in regard to statutory crimes even where the statutory definition did not in terms include it . . . , there has been a modification of this view in respect to prosecutions under statutes the purpose of which would be obstructed by such a requirement.[5]

Among the examples are statutory rape, the narcotic laws and the Federal Food, Drug, and Cosmetic Act. Dealing with the latter Act, the Supreme Court, in the *Dotterweich* decision, said:

> The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger.[6]

PRESIDENT EISENHOWER OFFERS ANTITRUST PROPOSALS

President Eisenhower, in his economic report transmitted to Congress on January 20, 1958, stated:

". . . a further means by which Government can promote the proper interests of small business concerns, and of the community in general, is by eliminating barriers to open and fair competition. This requires vigorous enforcement of the antitrust laws. Certain improvements in these laws should be made.

"The recommendation has been made in previous Economic Reports that notice to the antitrust agencies should be required when businesses of significant size that are engaged in interstate commerce propose to merge. Such a law would facilitate antitrust enforcement by providing an automatic notification to the responsible agencies of merger plans.

"Other measures also are needed to strengthen the administration and enforcement of the antitrust laws and to foster a competitive environment: Federal regulation should be extended to bank mergers accomplished through the acquisition of assets; in antitrust cases, the Attorney General should be empowered to issue civil investigative demands for the production of necessary documents without the need of grand jury proceedings; cease-and-desist orders issued by the Federal Trade Commission for violations of the Clayton Act should be made final unless appealed to the courts; and the Federal Trade Commission should be authorized, in merger cases where it believes violation is likely, to seek a preliminary injunction."

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[4] See Clark and Marshall, *A Treatise on the Law of Crimes* (4th Ed., 1940), pp. 56-145; Sayre, "Public Welfare Offenses," 33 *Columbia Law Review* 55 (1933).

[5] *U. S. v. Balint*, 258 U. S. 250, 251-252 (1922).

[6] *U. S. v. Dotterweich*, 320 U. S. 277, 280-281 (1943).

The Scientists' Forum

By BERNARD L. OSER

Director, Food and Drug Research Laboratories, Inc.

What's in a Name?

Notwithstanding the fact that it is generally understood what is meant by "chemical additives" to foods, the difficulty of arriving at a suitable legal definition has been one of the factors responsible for retarding the adoption of new legislative controls. The variety of names applied to these substances illustrates the complexity of the problem. Some of the proposed bills call them chemical additives, others call them food additives; in certain instances they are characterized as intentional or incidental (that is, nonintentional); in some cases, the adjective "new" is applied.

Among scientists and technologists, "food additive" is preferred to "chemical additive" not just for semantic reasons, but because it is more precise. Additives are used in various kinds of products and are commonly identified by the products in which they are incorporated. Battery additives and gasoline additives have lately been in the public limelight. All additives are intrinsically chemical in nature. Hence the term "chemical additive" is not as specific or meaningful as "food additive."

Furthermore, it is reasonable for the consumer to expect and demand that food additives be safe under conditions of use; at least, the purpose of establishing better regulatory control is to insure (some would say "restore") public confidence in the safety of foods. But whether justified or not, laymen instinctively attach a sinister significance to the word "chemical" and are more prone to believe that all chemicals are poisonous than that all foods are chemicals.

The difficulties go beyond the mere name, however. To define a food additive in terms of lack of recognized safety—as most of the proposed bills do—is to imply that when such a substance has been recognized or established to be safe, it ceases to be a food additive. In other words, both sodium benzoate or calcium propionate are antimicrobial agents, "generally recognized" by qualified experts as safe

and officially sanctioned for many years. Nevertheless, they would not be food additives under these definitions.

The obvious intent is to distinguish between unproved (possibly unsafe) additives, on the one hand, and approved (without reasonable doubt, safe) additives, on the other. Newness does not make this distinction. Neither an old food additive whose safety has never been tested nor a new food additive whose safety is universally recognized could conform to the definitions of "new food additive" in H. R. 8390, for example.

The major aim in amending the law governing additions to food is to require prior testing. This implies ultimate acknowledgement that the proposed use will be safe. Hence, it is suggested that the definition be established for "unproved" food additives which, upon meeting the appropriate standards, could be described as "permitted" or "approved."

FOODS—PRICE DISCRIMINATION; PROMOTIONAL ALLOWANCES; COMBINING OR CONSPIRING

Dairy products . . . A distributor of dairy products is charged with discriminating among its customers in prices. It is alleged that, through the distributor's monthly quantity-discount schedule, some large chains have been charged lower prices than competing retailers. The company allegedly favors large multistore customers by aggregating the purchases of all affiliated stores regardless of individual purchases. The distributor is also charged with discriminating in the granting of promotional allowances. (Issued December 31, 1957; released January 16, 1958.)

Carbonated beverages . . . Charges that a company selling carbonated beverages gave unlawful promotional allowances to favored customers indirectly through major radio-TV network intermediaries are dismissed for lack of potential proof. (Released January 8, 1958.)

Tuna . . . Charges that a boat-owner association engaged in a conspiracy to fix tuna prices and to prevent competition in the West Coast tuna industry would be dismissed without prejudice. The hearing examiner, noting that substantially all of the West Coast tuna industry has been ordered to stop fixing prices, ruled that "it would not be in the public interest to expend the time and money which would be necessary to try the entire case for the purpose of securing an order to cease and desist against this single group of respondents." (Released January 17, 1958.)—CCH TRADE REGULATION REPORTS ¶ 26,952; 26,927; 26,950.

WASHINGTON—Continued from page 70

In the Public Health Service

National Advisory Committee on Radiation.—The establishment of a National Advisory Committee on Radiation was announced on February 12 by Dr. Leroy E. Burney, Surgeon General of the Public Health Service. The committee will advise the Surgeon General on the further development of service programs dealing with public-health aspects of radiation from all sources.

In announcing establishment of the committee, Dr. Burney said that "the development of adequate safeguards against the hazards of radiation must be regarded as an increasingly important public health responsibility."

Present activities of the service in this field include research; epidemiological studies; radiation monitoring of milk, water and air; and technical assistance to the states on radiation safety measures.

The President's budget for the United States Department of Health, Education, and Welfare for the next fiscal year requests for the Public Health Service's radiological health activities a 50 per cent increase over funds available during the current year.

Last August, the Surgeon General appointed Dr. Russell H. Morgan, professor of radiology, Johns Hopkins University Medical School, and radiologist-in-chief of Johns Hopkins Hospital, as special consultant on the public-health aspects of radiation. Dr. Morgan will serve as chairman of the new committee, which will hold its initial meeting March 13.

In the Federal Trade Commission

Increased Enforcement Activities.—Increased antitrust and trade regulatory law enforcement activity has been reported by both the antitrust division of the Department of Justice and the Federal Trade Commission.

Assistant Attorney General Victor R. Hansen, head of the antitrust division, in his annual report to the United States Attorney General, stated that a significantly greater number of cases were filed in 1957 than had been filed in any of the past five calendar years. He also noted that actions charging price fixing on important consumer items occupied a prominent role in the enforcement of the antitrust laws during the year, according to a Department of Justice release.

The Federal Trade Commission, in its annual report for fiscal year 1957, describes postwar peaks in new actions against both deceptive and monopolistic business practices. It notes that the year ending last June 30 was characterized as one in which the Commission had mobilized its efforts to combat illegal concentrations of power in business, particularly those resulting from illegal mergers. The number of anti-merger complaints filed during the year equaled the total issued by the Commission in the previous five years following the 1950 amendment of Section 7 of the Clayton Act, according to the Commission. Also highlighted by the report were totals of 242 formal complaints alleging law violations and

179 orders to cease and desist, as compared to 192 complaints and 172 orders the preceding year. Copies of the 1957 annual report may be obtained from the Superintendent of Documents, U. S. Government Printing Office, Washington 25, D. C., at 40 cents per copy.

Antitrust and Trade Regulation Bills.—Bills which would permit the institution of private antitrust actions for violations of Section 3 of the Robinson-Patman Act have been introduced in Congress. If enacted into law, they would have the effect of overturning the recent United States Supreme Court decisions in the *Nashville Milk Company* and *Safeway Stores, Inc.* cases (reported in CCH TRADE REGULATION REPORTS, at ¶ 68,915-68,916), holding that a private party cannot maintain an antitrust action based on violations of Section 3 of the act.

Also, the Senate Committee on Interstate and Foreign Commerce has announced that a special subcommittee will be appointed to hold hearings on H. R. 469, which would prohibit the misbranding and false advertising of the fiber content of textile fiber products. This bill was passed by the House in August, 1957.

• "QUITE A CHORE" •

The proof of the pudding is in the eating, but as one federal judge once pointed out (in *U. S. v. 298 Cases, etc., Ski Slide Brand Asparagus*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7131), one sometimes obtains such evidence at his own hazard:

"Defendant is an asparagus packer. One of his products is the center cut of the asparagus. This retails for 20¢ per can (1 lb. 3 oz.) containing 95 to 100 cuts, as compared with 40 to 45 cents per can for the choicer tips.

"The Government contends that defendant's center cuts are fibrous and woody beyond the permissible limits . . . . Three witnesses for the Government said that they had each eaten a can (or attempted to) . . . . The composite of their testimony was that 25% or more of the cuts were inedible, and the Government's witnesses condemned them as a food product.

"On the other hand, the Director of Mary Cullen's Cottage found only 5 or 6 pieces out of 100 that she had to lay aside. Confronted with this conflict in testimony, I obtained counsels' consent to eat a can. This I have done, although I confess had I understood all the difficulties of the undertaking I might not have been so bold.

"To eat a can of asparagus, hand-running, as the saying is, is quite a chore. I took three days to eat the can. That, I can now state, is as much as an old protein user should attempt on his first venture into herbalism. I suspect the Government witnesses tried to eat their cans all at one time, and that may explain the severity of their judgment about defendant's asparagus. I can see where after 50 or 60 cuts, eaten without spelling oneself, one might become very particular.

"My test more than confirmed Miss Laughton's good opinion of the cuts. She found 5 or 6 per cent. inedible, whereas I ate all of my can, and felt that I was helped by it. There was one runty, tough piece and two or three slivers, but I treated them as de minimis.

"I agree . . . that this is an excellent product, particularly considering its low price. Not everybody in this country can 'keep up with the Joneses' and eat only asparagus tips. Indeed it seems strange to me that the Government should be interested in keeping from the market a moderately priced, wholly nutritious food product."

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